United States Court of Appeals
for the
District of Columbia Circuit

TRANSCRIPT OF RECORD

BRIEF AND APPENDIX FOR APPELLANTS

IN THE

United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA.

UNITED STATES
COURT OF APPEALS FOR
DISTRICT OF COLUMBIA

FILED MAR 10 1943

No. 8267

905

WALTER F. STRAUB AND W. F. STRAUB & COMPANY, A CORPORATION, *Appellants*,

v.

CONWAY P. COE, COMMISSIONER OF PATENTS,
Appellee.

Appeal from the District Court of the United States for the District of Columbia.

P. E. HENNINGER,
Washington, D. C.,
Attorney for Appellants.

PARKER, CARLSON, PITZNER & HUBBARD,
One North La Salle Street,
Chicago, Ill.,
Of Counsel.

PRESS OF BYRON S. ADAMS, WASHINGTON, D. C.

INDEX.

Page

I. Jurisdictional Statement 1

II. Statement of the Case 1

III. Statement of Points 3

IV. Summary of Argument 4

V. Argument 6

Conclusion 12

CASES CITED.

Canadian-American Pharmaceutical Company v. Coe, 75 U. S. App. D. C. —; 126 F. (2d) 847.......... 5, 8

Eibel Process Company v. Minnesota and Ontario Paper Company, 67 L. Ed. 523; 261 U. S. 68...... 5, 10

Ex parte Armat, 269 O. G. 189 (1918) 5, 8

Ex parte Armstrong (C. C. P. A. 1936); 83 F. (2d) 924; 30 Pat. Q. 24 .... 5, 8

Ex parte James H. Sherts, 22 Pat. Q. 261............ 5, 10

Western Tube Company v. Rainier, 156 F. 49........ 5, 10

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Appeal from the District Court of the United States for the District of Columbia.

BRIEF FOR APPELLANT.

I. JURISDICTIONAL STATEMENT.

The United States Court of Appeals for the District of Columbia has jurisdiction of this appeal because it was duly taken from a final judgment of the United States District Court for the District of Columbia in a suit brought by Walter F. Straub and W. F. Straub & Company, appellants, under Section 4915 of the Revised Statutes (U. S. C. Title 35, Section 63) against appellee, a resident of the District of Columbia, in his official capacity as Commissioner of Patents.

II. STATEMENT OF THE CASE.

The judgment of the District Court dismissed plaintiffs' complaint seeking a patent under Section 4915 of the Revised Statutes.

The invention in suit is defined in claims 1, 2, 3, 4, 5, 8, and 10 of application for patent Serial No. 141,439, filed May 8, 1937 (Appellants' App. 6).

The substance of the claimed invention is a food product comprising honey and vitamin D which, when taken internally as a food, will stimulate calcium metabolism in the body in order to insure proper bone formation and growth.

The claims that were rejected by the Commissioner of Patents are the following:

1. A food product comprising honey and vitamin D.
2. A food product comprising honey and a vitamin D concentrate.
3. A food product comprising a solution of honey and a vitamin D concentrate in the form of an alcoholic extract.
4. A food product containing honey and an oil concentrate of vitamin D emulsified in the honey.
5. A food product containing honey and finely divided crystals of vitamin D dispersed therein.
8. A food product comprising honey and vitamin D concentrated in a base immiscible with water, said concentrate being dispersed throughout the honey.
10. A food product comprising honey and concentrate containing vitamin D, said concentrate being soluble in honey.

The prior patents cited in the Patent Office and relied on in the District Court are as follows:

Steenbock	1,680,818
Rasky	1,892,902
Crane	1,911,882
Bresnick	2,007,108
Hall	2,022,464
Hooper	2,030,792

It has been known heretofore that the function of vitamin D, known as the anti-rachitic vitamin, is to increase and preserve the normal balance of calcium salts in the bones of the body and thus prevent rachitis, or the disease commonly known as rickets. In accordance with this knowledge vitamin D has been added to medicine and to foodstuffs of various kinds and found to be effective for the purpose stated.

Prior to the Straub invention it has *not* been known or suggested that any unusual result would be effected by the addition of vitamin D to honey (Appellants' App. 78). Straub found by experiment and test that a food product containing honey and vitamin D has an unusually large and unexpected beneficial effect upon calcium retention and assimilation in the body (Appellants' App. 52, 75). The exact nature of the function is not understood, but the fact is established that the combination of honey and vitamin D has anti-rachitic properties to an extraordinary extent and, when taken internally as a food, produces an extremely active calcium retaining and assimilating condition in the body. Thus calcium salts taken into the body in the normal diet may be available and utilized in the formation of bone *to a much greater extent than would be expected with the use of vitamin D alone.*

While the application for patent was pending before the Patent Office, affidavits were submitted to show that the improved function of vitamin D when mixed with honey is quite marked and totally unexpected (Appellants' App. 9, 11, 17, 25). The proofs that were offered were not acceptable to the Commissioner of Patents and he held that the applicant had not established that honey and vitamin D coact or cooperate in any unusual or unexpected manner.

The claims were further rejected in the Patent Office as failing to distinguish over Bresnick Patent No. 2,007,108.

III. STATEMENT OF POINTS.

The District Court was in error with respect to the following points that are to be argued here:

1. In sustaining and adopting the decision of the Patent Office that applicant had not established that honey and vitamin D coact or cooperate in any unusual or unexpected manner;

2. In sustaining and adopting the decision of the Patent Office that the Straub claims do not substantially distinguish over the Bresnick Patent No. 2,007,108;

3. In holding that claims 1 and 2 of the Straub application are either anticipated by the Bresnick Patent No. 2,007,108 or unpatentable thereover;

4. In holding that claim 1 of the Straub application is either anticipated by the Rasky Patent No. 1,892,902 or unpatentable thereover;

5. In holding that claims 1, 2, 3, 4, 5, 8, and 10 of the Straub application are not patentable over the patents to Steenbock No. 1,680,818, Rasky No. 1,892,902, and Crane No. 1,911,882, particularly in view of the patents to Hall No. 2,022,464 and Hooper No. 2,030,792;

6. In holding that claims 1, 2, 3, 4, 5, 8, and 10 of the Straub application express a mere aggregation rather than a patentable combination;

7. In failing to authorize and direct the Commissioner of Patents to issue to plaintiffs a patent upon the Walter F. Straub Application for Patent Serial No. 141,439, filed May 8, 1937, for Food Product.

IV. SUMMARY OF ARGUMENT.

A

The decision of the Board of Appeals of the Patent Office (Appellants' App. 35) refusing a patent was based in part on the premise that the combination of honey and vitamin D failed to cooperate in any unusual and unpredictable manner. The decision was reached without full regard to the uncontradicted evidence that was presented. The uncontradicted evidence before the Board of Appeals and before the District Court (which was not before the Board of Appeals of the Patent Office) fully establishes that the combination of honey with vitamin D increases the calcium-assimilating function of the vitamin to a remarkable degree and that this result was wholly unexpected and unpredictable before the Straub invention. This evidence required in and of itself a reversal of the decision of the Board of Appeals by the District Court; and the failure of the District Court to enter findings in accordance with the uncontradicted evidence was obvious error.

> *Canadian-American Pharmaceutical Company* v. *Coe*, 75 U. S. App. D. C. ——; 53 U. S. P. Q. 92; 126 F. (2d) 847.
> *Ex parte Armstrong* (C. C. P. A. 1936), 83 F. 2d. 924; 30 Pat. Q. 24.
> *Ex parte Armat,* 269 O. G. 189 (1918).

B

The evidence shows no teaching by anyone that the addition of honey to vitamin D would improve the activity of the vitamin. None of the patents to Steenbock, Rasky, Crane, Hall, or Hooper in any way suggests the combination of honey and vitamin D; these patents having been referred to for purely ancillary disclosures. Therefore, only the Bresnick Patent No. 2,007,108 can be relied on as an anticipation of the invention.

C

The patent to Bresnick 2,007,108 mentions the use of honey as a less desirable flavoring substance for a medical preparation comprising a dehydrated vegetable fat, a sweetening agent, and a vitamin D containing fish liver oil. There is no evidence that Bresnick sought to render the vitamin more active, nor is there evidence that Bresnick knew that the addition of a substantial portion of honey to vitamin D would result in unexpected activity of the vitamin. Therefore any evidence that may be in the Bresnick patent that honey may be added to vitamin D teaches a totally different purpose and is wholly without appreciation of the principle upon which the Straub invention is based. This fact alone requires the withdrawal of the Bresnick patent and the allowance of the claims.

> *Eibel Process Company* v. *Minnesota and Ontario Paper Company,* 67 L. Ed. 523; 261 U. S. 68;
> *Western Tube Company* v. *Rainier,* 156 F. 49; and
> *Ex parte James H. Sherts,* 22 Pat. Q. 261.

V. ARGUMENT.

The holding that the claims of the application are drawn to an aggregation is predicated on the finding that the applicants have not established that honey and vitamin D coact or cooperate in any unusual or unexpected manner (Appellants' App. 39). An aggregation has been variously defined but it is accepted as involving the association of elements or substances in a relation wherein each element or substance performs no more than its expected function. The claims under consideration here are not aggregative.

In the present case there is a new calcium-retaining value that is not attributable to vitamin D alone (Appellants' App. 52, 57, 75). There is no calcium-retaining property attributable to honey alone (Appellants' App. 79). *We submit that it is, therefore, possible to draw only the conclusion that the combination of the two substances is responsible for the new and unexpected result.* The result cannot be aggregative or additive when honey alone has little or no calcium content or calcium-assimilating value that can be added to that of the vitamin.

These conclusions are fully supported by the testimony of Dr. F. W. Schlutz who is an eminent authority in pediatrics and bio-chemistry. The testimony of Dr. Schlutz is fully corroborated by his assistant, Dr. E. M. Knott, who conducted experiments extending over a five-year period on fourteen infants and involving a total of 120 metabolism periods (Appellants' App. 45, 56, 73). During the experiments that substantiate the Straub claims, milk, water, and vitamin D in combination with either honey or Karo corn syrup was fed to the subjects under scientifically controlled conditions for the purpose of determining the calcium metabolism under conditions of feeding that included honey and vitamin D on the one hand, and vitamin D and corn syrup on the other hand. The calcium retention was determined by subtracting the amount of calcium the infant secreted in his feces and urine during a given metabolism period, from the total calcium given to him in his food (Appellants' App. 53).

Individual tests, of course, were unacceptable because of idiosyncrasies in the subject or because of some other difference in operating conditions. Therefore the experiments were conducted for a sufficiently long time to obtain averages that were dependable (Appellants' App. 54, 57, 63, 74). The capacity of the human body to absorb calcium may vary from day to day. No two bodies will have the same calcium-retaining capacity at the same time. The nature of the experiments precludes the possibility of running simultaneous tests under identical conditions. Therefore it is impossible to measure the calcium-retaining effect of two substances on the same body at the same time. For this reason average results derived from a series of tests afford the only sound basis from which conclusions can be drawn. The fact that the tests were conducted over a period of five years and included 120 metabolism periods is evidence of the integrity of the technicians conducting the test and resulted in averages that are dependable. *The averages alone indicate that the honey and vitamin D diet has a substantially greater calcium-retaining effect than a corn syrup and vitamin D diet.*

It was found by Dr. Schlutz that the average calcium retention from the honey and vitamin D diet is definitely and materially higher than the retention from Karo corn cyrup and vitamin D, and that in practically all individual instances the same result is found to be true (Appellants' App. 57). Calcium retentions from Karo corn syrup for a typical group of periods averaged 25.2 milligrams per kilogram of body weight as compared with 33.7 milligrams per kilogram of body weight when honey was given, an increase of approximately 34 per cent (Appellants' App. 14).

It is submitted that the affidavits presented before the Patent Office and the testimony of Drs. Schlutz and Knott before the District Court fully establish the fact that a composition consisting of honey and vitamin D when consumed in the digestive organs in the presence of a calcium-containing food results in a marked increase in the power of the vitamin D to assist the body in assimilating the calcium from the calcium-containing food.

It is improper to require unusual and difficult proofs as a condition precedent to the grant of a patent. This Court has held in the case of *Canadian-American Pharmaceutical Company* v. *Coe* that evidence of utility of ensol for the relief of pain in cancer cases was sufficient to warrant the grant of a patent under the patent laws. Other courts and the Patent Office itself have repeatedly given full credit to respectable evidence that novel combinations of elements, in themselves separately old, result in such unexpected and unpredictable results as to demonstrate invention. The Commissioner of Patents himself has held that claims should be allowed in view of affidavits by experts that the results claimed were accomplished. *Ex parte Armstrong,* (C. C. P. A. 1936), 83 F. 2d 924, and *Ex parte Armat,* 269 O. G. 189.

The art cited by the Patent Office seems to us quite irrelevant. The patent to Steenbock 1,680,818 (Appellants' App. 95) relates to the irradiation of foodstuffs by subjecting such foodstuff to actinic rays thereby rendering the substance so treated anti-rachitically active. This patent does not mention honey nor does it mention vitamin D as such. There is no teaching in the Steenbock patent that the composition of honey and vitamin D will enhance the calcium-absorbing function of the vitamin.

The patent to Rasky No. 1,892,902 (Appellants' App. 100) discloses a mixture of butter and honey to produce a homogeneous spread resembling commercial butter. Butter contains only a negligible amount of vitamin D (Appellants' App. 60) and there is no disclosure of vitamin D in the Rasky patent other than the negligible amount that may be contained in the butter. There is no teaching in the Rasky patent that the composition of honey and vitamin D will enhance the calcium-absorbing property of the vitamin.

The Crane Patent No. 1,911,882 (Appellants' App. 102) discloses a food product consisting of granulated honey and dried apricots. There is no mention made in the Crane specification of vitamin D. There is no vitamin D in honey (Appellants' App. 79). There is no vitamin D in apricots (Appellants' App. 60). There is no teaching in the Crane patent that the composition of honey and vitamin D will enhance the calcium-absorbing properties of the vitamin.

The Hall patent No. 2,022,464 (Appellants' App. 107) discloses an oil base vitamin concentrate that has been emulsified to produce a palatable product easily incorporated into food products. The specification does not mention honey. There is no teaching in the Hall patent that the composition of honey and vitamin D will enhance the calcium-absorbing property of the vitamin.

The Hooper patent No. 2,030,792 (Appellants' App. 109) discloses a water-miscible vitamin D preparation obtained by the use of an alcohol as a solvent. There is no mention of honey in the Hooper specification. There is no teaching in the Hooper patent that the composition of honey and vitamin D will enhance the calcium-absorbing properties of the vitamin.

The patent to Bresnick No. 2,007,108 (Appellants' App. 104) was the only patent relied on by the Board of Appeals of the Patent Office and therefore the disclosure deserves careful attention. Bresnick discloses a medical preparation, *not suitable as a food* (Appellants' App. 60), comprising fish liver oils, to which he adds one or several of a number of masking or flavoring ingredients, the preferred flavoring substances being those having the least moisture and which in themselves are fairly stable such as spices, barks, powdered and essential flavorings. In a single sentence Bresnick adds the afterthought that he has found grain honey a satisfactory flavor. There is no mention or suggestion in the patent that the combination of honey and vitamin D is a particularly desirable one. The purpose of the grain honey in the Bresnick composition is to eliminate the undesirable flavor of the fish liver oils. *The use of honey as a flavoring element, in place of some other flavoring element, is disclosed as one of Bresnick's less important alternatives which clearly shows that he never contemplated the combination of honey and vitamin D in substantial proportions or that he knew such combination would produce any unusual result.* We submit that the Bresnick patent does not disclose applicants' combination such as to effectively anticipate the invention. At best, Bresnick's composition is nothing more than a chance composition with no appreciation by him whatsoever of the actual dietary benefits that are obtained from the combination of honey and vitamin D. Without such appreciation there can be no anticipation. In the past both the Patent Office and the courts have consistently held that an accidental disclosure without appreciation of an achieved invention is not a bar to a patent on a subsequent application that fully discloses the invention and teaches a new and useful result. The following cases are directly in point: *Eibel Process Company* v. *Minnesota and Ontario Paper Company,* 67 L. Ed. 523; 261 U. S. 68; *Western Tube Company* v. *Rainier,* 156 F. 49; and *Ex parte James H. Sherts,* 22 Pat. Q. 261.

The holding that claims 1 and 2 of the Straub application are either anticipated by the patent to Bresnick 2,007,108 or unpatentable thereover is improper for the reason that the Bresnick patent merely by chance mentions the use of grain honey as a flavoring for vitamin-containing oils and in no way teaches that the calcium-absorbing properties of vitamin D can be improved by its combination with honey.

The holding that claim 1 of the Straub application is anticipated by the patent to Rasky No. 1,892,902 is improper because the Rasky patent has no disclosure of vitamin D and honey. The patent merely discloses a honey and butter composition as a substitute for whole butter and the amount of vitamin D in butter is so insignificant as to warrant very little consideration (Appellants' App. 60).

The holding that claims 1, 2, 3, 4, 5, 8, and 10 of the Straub application are not patentable over the patent to Steenbock 1,680,818, Rasky No. 1,892,902, Crane No. 1,911,882, particularly in view of the patents to Hall No. 2,022,464 and Hopper No. 2,030,792 is improper because none of these patents discloses a food product consisting of vitamin D and honey.

We submit that the prior art patents are entirely devoid of a disclosure that teaches the combination of honey and vitamin D for the purpose of increasing the activity of the vitamin and in the absence of such teaching, these patents cannot be a bar to a patent on the Straub application. The failure of the prior patents to teach anything useful with respect to the Straub invention is particularly underlined by the fact that Straub has spent years in research to establish without preadventure of doubt the useful results flowing from his discovery.

There is no inhibition to the grant of patents based on discoveries in chemistry. Some of the most useful inventions have been in this field. For more than fifteen years we have been enjoying the advantage of the better engine performance that resulted from Thomas Midgley's simple addition of tetraethyl lead to gasoline to remove the "knock" and improve the intended performance of the gasoline. Is Straub in a different position because his invention is in the field of bio-chemistry? The Straub invention is new, the prior patents do not disclose it; the Straub invention is useful, the evidence proves it; the Straub invention is patentable because the useful results that can be obtained through its knowledge are unexpected and unpredictable. The fact that Straub's composition improves the intended performance of vitamin D in the human body, it seems to us, is no less important than the addition of tetraethyl lead to gasoline for the purpose of improving the intended performance of gasoline in an automobile engine.

There has been some intimation that the results obtained by the combination of honey and vitamin D are no different from the results obtained by using the substances separate. Dr. Schlutz has stated that the optimum results are secured when the honey and vitamin D are both active in the digestive tract at the same time (Appellants' App. 64, 68). This point, however, is a moot question. The claims of the Straub application are directed to a food product and not to a process of treating diseases. The claims are all directed to a food product comprising honey and vitamin D. This is a product that constitutes a saleable article of commerce and should anyone desire to procure honey and vitamin D separately and consume portions of each in sequence, there, of course, would be no infringement of the claims because the principle cannot and is not being claimed by Straub. His claims include only the application of the principle of his discovery to a composite product comprising the honey and the vitamin.

CONCLUSION.

The findings and conclusions of the District Court were reached in disregard of the uncontradicted evidence. The decision was based in part on an erroneous application of prior patents. The decision of the District Court is unsound and improper in point of clearly established legal precedents. It is respectfully submitted that the patent should be issued in the form sought.

Respectfully submitted,

P. E. Henninger,
Washington, D. C.,
Attorney for Appellants.

Parker, Carlson, Pitzner & Hubbard,
One North LaSalle Street,
Chicago, Illinois,
Of Counsel.

APPENDIX

INDEX TO APPENDIX.

Page

Complaint 2

Answer 5

Straub application and claims 6

Straub Affidavit 9

Schlutz Affidavit 11

Schlutz Affidavit 17

Examiner's Statement 20

Schlutz Affidavit 25

Examiner's Statement under Rule 138 33

Decision of Board of Appeals 35

Findings of Fact and Conclusions of Law 37

Judgment 40

Notice of Appeal 40

Testimony of Dr. F. W. Schlutz 49

Testimony of Dr. E. M. Knott 69

Appellant's Exhibit No. 2 81

Appellee's Exhibit No. 1 93

IN THE

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v.

CONWAY P. COE, COMMISSIONER OF PATENTS, *Appellee.*

Appeal from the District Court of the United States for the District of Columbia.

APPENDIX TO BRIEF FOR APPELLANTS.

I.

PLEADINGS, DOCKET ENTRIES AND OTHER PAPERS DESIGNATED BY APPELLANTS.

1 Endorsed: Filed Aug 20 1940 Charles E. Stewart, Clerk

In the United States District Court
For the District of Columbia

Civil Action No. 8069

Walter F. Straub and W. F. Straub & Company, a Corporation, 5514 Northwest Highway, Chicago, Illinois, *Plaintiffs,*

v.

Conway P. Coe, Commissioner of Patents, *Defendant.*

Complaint

(Equitable Relief Sought)

For Issuance of Patent

1. The jurisdiction of this Court is based upon the patent laws of the United States and in particular upon Revised Statutes of the United States, Section 4915 (F. C. A. 35: 63).

2. The Plaintiff Walter F. Straub is a citizen of the United States and a resident of Winnetka, Illinois. The Plaintiff W. F. Straub & Company is a corporation of Illinois and has its principal office and place of business in the City of Chicago in said State. The Defendant Conway P. Coe is the Commissioner of Patents of the United States, an official resident of the District of Columbia, and is sued as Commissioner of Patents of the United States.

3. The Plaintiff Walter F. Straub is the sole, true, first and original inventor of a certain food product adapted to stimulate calcium metabolism in the body to insure proper bone formation and growth. The said invention is more

particularly set forth in the several claims of the
2 application for patent hereinafter recited.

4. On, to wit, the 8th day of May, 1937, Plaintiff Walter F. Straub filed an application for patent on the aforesaid food product, which application was given the Serial No. 141,439.

5. Coincidentally with the filing of said application for patent, the Plaintiff Walter F. Straub executed, and filed in the Patent Office, an assignment of the said application, the invention covered thereby, and the patent or patents that may issue thereon, to the corporate Plaintiff W. F. Straub & Company; and by said assignment did authorize and request the Commissioner of Patents to issue said letters patent to the said assignee.

6. The said application was filed in accordance with the laws of the United States and the rules of the Patent Office.

7. The said application has been duly prosecuted in accordance with the laws of the United States and the rules of the Patent Office. Profert of a copy of said application containing copies of the proceedings in the Patent Office is hereby made.

8. The said application has been passed upon by the Primary Examiner of the Patent Office, who rejected all the claims in said application as follows:

1. A food product comprising honey and vitamin D.

2. A food product comprising honey and a vitamin D concentrate.

3. A food product comprising a solution of honey and a vitamin D concentrate in the form of an alcoholic extract.

3 4. A food product containing honey and an oil concentrate of vitamin D emulsified in the honey.

5. A food product containing honey and finely divided crystals of vitamin D dispersed therein.

8. A food product comprising honey and vitamin D concentrated in a base immiscible with water, said concentrate being dispersed throughout the honey.

10. A food product comprising honey and concentrate containing vitamin D, said concentrate being soluable in honey.

9. The applicant appealed from the decision of the Primary Examiner to the Board of Appeals of the Patent Office and said Board of Appeals affirmed the rejection of the claims by the Primary Examiner in their decision dated February 21, 1940. No appeal or notice of appeal from said decision to the United States Court of Customs and Patent Appeals has been filed.

10. The invention as defined by the aforesaid claims is new and useful and patentable; but the Commissioner of Patents has refused, and continues to refuse, to issue a patent, in derogation of the rights of the Plaintiffs in the premises.

WHEREFORE the Plaintiffs pray that this Court adjudge that the Plaintiff Walter F. Straub is the first, true, sole and original inventor of the invention set forth in the above recited claims; that said invention is new, useful and patentable; and that the Plaintiff W. F. Straub & Company is entitled, according to law, to receive a patent for said invention.

WALTER F. STRAUB
W. F. STRAUB & COMPANY

By THEODORE A. HOSTETLER
Attorney for Plaintiffs,
14 & F Street, N. W.,
Washington, D. C.

Of Counsel:
PARKER, CARLSON, PITZNER & HUBBARD

C. PAUL PARKER.
LOWELL C. NOYES
1 North LaSalle Street,
Chicago, Illinois.

* * * * * * * * * *

5 *Answer to the Complaint.*

To the Honorable the Justices of the District Court of the United States for the District of Columbia.

1, 2. Defendant admits the allegations of paragraphs 1 and 2.

3. He admits that Walter F. Straub, claiming to be the sole, true, first and original inventor of a certain Food Product alleged to stimulate calcium metabolism in the body to insure proper bone formation and growth, filed application for Letters Patent therefor in the United States Patent Office. He admits that said application contains several claims. He denies that said claims recite inventive subject matter or that plaintiff is entitled to a patent containing said claims.

4, 5, 6, 7, 8, 9. He admits the allegations of paragraphs 4, 5, 6, 7, 8 and 9.

6 10. He admits that he has refused and still refuses to issue to plaintiffs a patent containing claims 1, 2, 3, 4, 5, 8 and 10. He denies that such refusal is wrongful, that the subject matter defined by said claims is new, useful or patentable, or that plaintiffs are lawfully entitled to a patent containing said claims since these claims are deemed to be unpatentable over the following prior patents and for the reasons as given in the statement of the examiner in answer to the appeal and the decision of the Board of Appeals, copies of which will be furnished at the trial:

Steenbock, 1,680,818, Aug. 14, 1928, Rasky, 1,892,902, Jan. 3, 1933, Crane, 1,911,882, May 30, 1933, Bresnick, 2,007,108, July 2, 1935, Hall, 2,022,464, Nov. 26, 1935, Hooper, 2,030,-792, Feb. 11, 1936.

Profert of copies of these patents is hereby made.

(Sgd.) W. W. COCHRAN
Solicitor, U. S. Patent Office,
Attorney for Defendant.

September 24, 1940.

I hereby certify that a copy of this Answer was mailed to the attorney for plaintiff on September 24, 1940.

(Sgd.) W. W. COCHRAN
Solicitor.

* * * * * * * * * *

104 Endorsed: Mail Division May 8, 1937 U. S. Patent Office

* * * * * * * * * *

105 *Specification and Claims of Straub*
Serial No. 141,439.

To all whom it may concern:

Be it known that I, Walter F. Straub a citizen of the United States, residing at Chicago in the County of Cook and State of Illinois have invented a certain new and useful Food Product, of which the following is a specification.

The invention relates to food products and has more particular reference to a honey food product.

A general object of the invention is to provide a food product containing honey and a vitamin which cooperates with newly discovered properties of honey to accomplish a beneficial effect on the human body.

Another object of the invention is to provide a food product which, when taken internally as a food, will stimulate or normalize calcium metabolism in the body in order to insure proper bone formation and growth and cure rachitic bone.

106 More specifically stated it is an object of the invention to provide a food product containing honey and vitamin D.

It is a further object of the invention to provide a palatable food product having an appetizing appearance and containing honey and vitamin D concentrate in the form of an alcoholic extract, minute crystals finely dispersed through the honey, or an oil solution emulsified with the honey.

Other objects and advantages will become apparent as the description proceeds.

It has been suggested heretofore that the function of vitamin D, known as the antirachitic vitamin, is to increase and preserve the normal deposition of calcium salts in the bones of the body and thus prevent rachitis, or the disease commonly known as rickets. In accordance with this belief vitamin D has been added to medicines and food stuffs of various kinds and found to be effective for the purpose stated.

Pure honey is a composition with the following average chemical analysis by weight:

Ingredient	Percent
Water	17.7
Dextrose (grape sugar)	34.0
Levulose (fruit sugar)	40.5
Sucrose (cane sugar)	1.9
Dextrins and Gums	1.5
Ash	0.18

107 This is an average composition of honey including
only the primary constituents. Other ingredients such as acids, pigments, beeswax, enzymes, rare sugars and other known substances are sometimes present in small quantities, but are difficult to demonstrate quantitatively. However, experiments fail to show that pure honey contains any vitamin D naturally.

Prior to the present invention it has not been known or suggested that any unusual result would be effected by the addition of vitamin D to honey. I have found by experiment and test that a food product containing honey and vitamin D has an unusually large and unexpected beneficial effect upon calcium retention and assimilation in the body. The exact nature of this function is not understood, but the fact is established that this combination of honey and vitamin D has antirachitic properties to an extraordinary extent and, when taken internally as a food, produces an extremely active calcium retaining and assimilating condition
in the body. Thus calcium salts taken into the body
108 in other foods may be made available and utilized in
the formation of bone to a much greater extent than would be expected with the use of the ordinary vitamized food product.

Although the vitamin D may be added to the honey in any suitable manner or form, it is my preference to employ a vitamin D concentrate in the form of an alcoholic extract. Such a solution is readily miscible with honey which has an aqueous base. Thus any problems of mixing and miscibility are eliminated.

There are, also, several vitamin D concentrates available in oil solutions which are not miscible with a material having an aqueous base such as honey. However, it is possible, in using one of these oil concentrates, to form a stable emulsion, the honey acting as the dispersing phase and the oil as the dispersed phase.

A third method of combining honey and vitamin D involves the addition of the latter in the form of finely divided crystals and agitating the resulting mixture so as to thoroughly disperse the crystals throughout the body of the honey.

109 In any of the above-mentioned forms by which vitamin D may be combined with honey, one hundred U. S. P. XI units of vitamin D to the ounce of honey has been found to be a satisfactory concentration, although this figure may be varied over a wide range in accordance with the use or as desired.

The addition of a pure concentrate of vitamin D, such as an alcoholic extract or finely divided crystals, to honey results in a product which in no way detracts from the appetizing appearance and palatability of pure strained honey, the addition of the vitamin causing no undesirable adulteration. Thus the product is admirably adapted for the treatment of infants and small children showing manifestations of rickets since it serves as a pleasing, nourishing and appetizing food and at the same time has a positive medicinal function. Also it is effective for the prevention of rickets and for maintaining a healthy bone condition in adults as well as children.

110 I claim as my invention:

1. A food product comprising honey and vitamin D.

2. A food product comprising honey and a vitamin D concentrate.

3. A food product comprising a solution of honey and a vitamin D concentrate in the form of an alcoholic extract.

4. A food product containing honey and an oil concentrate of vitamin D emulsified in the honey.

5. A food product containing honey and finely divided crystals of vitamin D dispersed therein.

* * * * * * * * * *

111 8. A food product comprising honey and vitamin D concentrated in a base immiscible with water, said concentrate being dispersed throughout the honey.

* * * * * * * * * *

10. A food product comprising honey and concentrate containing vitamin D, said concentrate being soluble in honey.

* * * * * * * * * *

112 In testimony whereof, I have hereunto affixed my signature.

(Inventor) WALTER F. STRAUB

* * * * * * * * * *

114 Mail Division U. S. Patent Office Feb 9, 1933

Paper No. 3 Division 63 Feb 10 1933

IN THE UNITED STATES PATENT OFFICE

Div. 63 Room 4888

Walter F. Straub
Food Product
Serial No. 141,439
Filed May 8, 1937

Affidavit

State of Illinois, County of Cook, ss:

Walter F. Straub, of lawful age, being duly sworn, deposes and says:

That he is a citizen of the United States residing in the City of Chicago, County of Cook and State of Illinois, and is a graduate of the University of Illinois, having taken a degree in organic and biological chemistry from that University.

That he is the President of the W. F. Straub & Company, 5520 Northwest Highway, Chicago, Illinois, the business of which is that of producing and marketing pure honey and allied products.

115 That, pursuant to a study and determination of the effect of the combination of honey and vitamin D on calcium retention and assimilation in the human body, a series of metabolism experiments were carried out by qualified and experienced technicians under his guidance, control and direction;

That the experiments were performed on infants from the ages of six weeks to six months and that said series of experiments was carefully controlled and supervised under uniform operating conditions and on the same group of infants throughout to obviate any misleading results due to biological variances in different individuals or due to inconsistencies or discrepancies in operating circumstances;

That honey and other sugars, such as Karo corn sugar, were fed to said infants sufficient to meet the necessary carbohydrate requirements of their dietary and to act as a vehicle for carrying vitamin D in standardized form mixed with the carbohydrates;

That in view of the above mentioned facts, he believes that the following conclusive results were positively ascertained as facts:

(1) While it is known that vitamin D added in various amounts mixed with ordinary carbohydrates, such as Karo
corn sugar, definitely increases calcium retention in
116 measurable amounts as determined by quantitative
analysis of the excreta, such retentions are definitely and materially enhanced when honey is the form of carbohydrate combined with the vitamin D.

(2) The use of the carbohydrate honey as a vehicle for feeding vitamin D substantially enhances the calcium retaining effect of vitamin D but no such enhancement takes place with other forms of carbohydrate vehicles such as Karo corn sugar, cane sugar or the like.

(3) Pure honey has definite properties when combined with vitamin D which materially enhance the calcium retaining effect of vitamin D.

Further deponent sayeth not.

WALTER F. STRAUB

Subscribed and sworn to before me this 5th day of February, 1938.

Armin A. Leibold,
Notary Public.

* * * * * * * * * *

124 Endorsed: Mail Division Nov 9 1938 U. S. Patent Office

Endorsed: Paper No. 5 Nov 11 1938 Division 63

In the United States Patent Office

Walter F. Straub
Food Product
Serial No. 141,439
Filed May 8, 1937

Div. 63
Room 4888

Affidavit

State of Illinois,
County of Cook, ss:

F. W. Schlutz, M. D., of lawful age, being duly sworn deposes and says:

That he is a citizen of the United States, residing in the City of Chicago, County of Cook and State of Illinois, that he is a graduate of the University of Maryland school of Medicine (1902), having taken the degree of Doctor of Medicine from that University, that he has done graduate work in pediatrics and biochemistry in Berlin, Strassbourg, Kiel, Paris and London, that for the six years prior to 1930 he was head of the department of pediatrics of the University of Minnesota school of Medicine and that since 1930 has been the chairman of the Department of Pediatrics of the Bobs Roberts Memorial Hospital for Children at the University of Chicago, Chicago, Illinois.

125 That, pursuant to a study of the relative effects of pure honey and other carbohydrates, when combined with vitamin D, on calcium retention and assimilation in the human body, a series of carefully controlled metabolism tests were performed by deponent.

That pure honey contains practically no calcium as shown by the fact that its average chemical analysis shows an ash content of 00.18%, and a small part of such ash comprises calcium or calcium salts.

That the tests were performed on infants during the first six months of their lives by carefully analyzing their food, urine and feces for periods of five consecutive days each at intervals throughout the investigation.

That each five day metabolism period was preceded by a preliminary period during which each infant received the identical dietary formula as was given during the metabolism period itself for the purpose of allowing the infant to adjust his body processes to the particular type of feeding used in the experiment.

That the infants during the metabolism periods and during the preliminary periods were given food containing only milk, water, vitamin D in the form of cod liver oil, and minerals to reduce the possible number of factors which
might effect the results, and in addition, either honey
126 or karo corn syrup was added to test the effects of
these two types of carbohydrates when other factors
were kept constant.

That calcium retention were determined by subtracting the amount of calcium the infant secreted in his feces and urine, during the given metabolism period, from the total calcium given to him in his food.

That the experiments were carefully controlled and supervised under uniform operating conditions and on the same group of infants throughout to obviate any misleading results due to biological variances in different individuals or due to inconsistencies or discrepancies in operating circumstances.

That, specifically, during these metabolism periods and their preliminary periods, the effect of honey when combined with vitamin D fed to the infant in the form of cod liver oil, was contrasted with karo corn syrup when so combined.

That the experiments were performed on various infants in the following manner (an illustration of experiments performed on one infant during the above mentioned six months' period):

Following a preliminary period, during which the infant received the same formula as given during the metabolism period, the infant was given food containing only 127 milk, water and minerals and in addition karo corn syrup and cod liver oil. During this metabolism period the calcium fed to the infant was carefully determined by quantitative analysis and the amount of calcium the infant secreted in the feces and urine was likewise determined by quantitative analysis and the calcium retentions were determined by subtracting the latter from the former. During a subsequent metabolism period, likewise preceded by a preliminary period, the identical dietary was fed to the infant with the exception of a substitution of honey for karo corn syrup. The calcium retentions were determined in an identical fashion during these periods. The level of vitamin D was maintained at a constant amount by feeding a constant quantity of cod liver oil. Any differences in calcium retentions were therefore due entirely to the type of carbohydrate fed in combination with the vitamin D.

That the above experiment was repeated with the same infant several times during the six months' period and was performed in a similar fashion several times during the same six months' period on the other infants.

That, if honey, when combined with vitamin D, has any advantage over other carbohydrates when combined with vitamin D in facilitating calcum utilization, it would become apparent during these periods.

128 That this advantage of honey, when combined with vitamin D, was found to be distinctly apparent, as is seen from the chart attached hereto and marked Exhibit A and forming a part of the present affidavit.

That the average calcium retention for the honey plus vitamin D periods is definitely and materially higher than that retention for the karo corn syrup plus vitamin D, and that in practically all individual instances the same result is found to be true. Calcium retentions for karo corn syrup for these periods averaged 25.2 milligrams per kilogram of body weight as compared with 33.7 milligrams per kilogram of body weight when honey was given, an increase of approximately 34 per cent.

That I, therefore, conclude on the basis of the actual figures obtained by quantitative analysis during the abovementioned carefully controlled metabolism periods, that honey, when combined with vitamin D, has the power to facilitate the utilization of calcium by an infant to a greater extent than when vitamin D is combined with other carbohydrates of the karo corn syrup type.

Further deponent sayeth not.

FREDERIC W. SCHLUTZ.

Subscribed and sworn to before me this 3rd day of November, 1938.

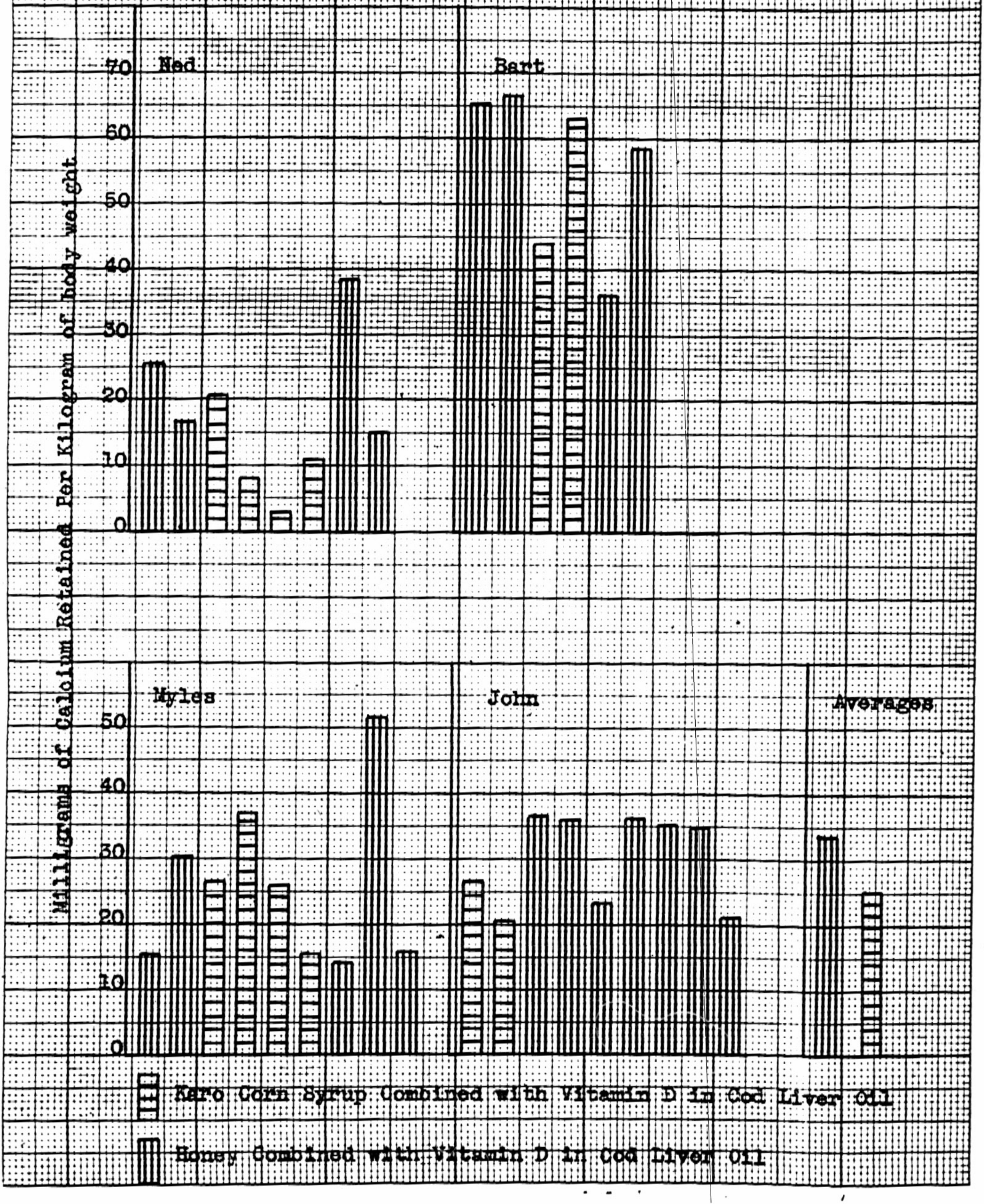
CAROLYN M. HENNING,
Notary Public.

My Commission expires June 8, 1942.

* * * * * * * * * *

EXHIBIT A

COMPARISON CHART SHOWING RELATIVE CALCIUM RETAINING VALUES FOR THE COMBINATION OF HONEY AND VITAMIN D AND THE COMBINATION OF KARO CORN SYRUP AND VITAMIN D (EACH COLUMN REPRESENTING A FIVE DAY METABOLISM PERIOD)



141 Endorsed: Mail Division Jul 26 1939 U. S. Patent Office

Endorsed: Paper No. 7 Jul 31 1939 Division 63

In the United States Patent Office

Div. 63
Room 4888

Walter F. Straub
Food Product
Ser. No. 141,439
Filed May 8, 1937

Affidavit

State of Illinois
County of Cook, ss.

F. W. Schlutz, M. D., of lawful age, being duly sworn deposes and says:

That he is a citizen of the United States, residing in the City of Chicago, County of Cook and State of Illinois.

That he is the deponent of the affidavit filed in the above entitled case and sworn to on November 3, 1938.

That the chart entitled "Comparison Chart Showing Relative Calcium Retaining Values for the Combination of Honey and Vitamin D and the Combination of Karo Corn Syrup and Vitamin D" accompanying and forming a 142 part of said affidavit is a compilation of actual experimental data obtained in tests on four children, Ned, Bart, Myles and John, and performed as set forth in said affidavit.

That each of the respective columns on said chart represents the calcium retained by the child designated over a five day metabolism period, that the vertically cross-hatched columns represent calcium retained when feeding the combination of honey and vitamin D in cod liver oil and that the horizontally cross-hatched columns represent the quantity of calcium retained when the combination of Karo corn syrup and vitamin D in cod liver oil was fed over five day metabolism periods.

That the former combination was fed to the child Ned four separate five day metabolism periods and the latter combination was fed to Ned four separate five day metabolism periods, that the calcium retained by Ned during these metabolism periods was measured as set forth in said affidavit and charted as indicated in the chart entitled Ned.

143 That the combination of honey and vitamin D in cod liver oil was fed to the child Bart four separate five day metabolism periods, and the combination of Karo corn syrup with vitamin D and cod liver oil was fed to Bart two separate five day metabolism periods, and measured and tabulated in the same manner as indicated in the chart entitled Bart.

That the combination of honey and vitamin D in cod liver oil was fed to the child Myles five separate five day metabolism periods, and the combination of Karo corn syrup with vitamin D in cod liver oil was fed four separate five day metabolism periods, and the calcium retention measured and charted in the same manner, as indicated on the chart entitled Myles.

That the child John was fed the combination of honey and vitamin D in cod liver oil seven separate five day metabolism periods and the combination of Karo corn syrup in cod liver oil was fed two separate five day metabolism periods and the results calculated and charted in the same manner, as indicated in the chart entitled John.

144 That the averages of all calcium retained by each child when feeding the combination of honey and vitamin D in cod liver oil in the separate five day metabolism periods were averaged and the result of said latter average charted as indicated in the chart entitled Averages, and that the averages of the calcium retained by each child when feeding the combination of Karo corn syrup with

vitamin D in cod liver oil were averaged and charted in said chart entitled Averages.

That there are variable human idiosyncrasies and conditions in each individual child which affect the amount of calcium which will be retained by that child at any given time regardless of the combination fed. In other words, that the condition of the child at a particular time is a factor affecting the amount of calcium which will be retained regardless of the combination fed.

That it is impossible to compile comparative data by feeding both combinations at the same time and that it is improbable that identical conditions would exist in a particular child during two separate metabolism periods as regards these variable idiosyncrasies.

145 That for the above reasons, in certain instances, due to these variable idiosyncrasies, Karo corn syrup may show a higher calcium retention than honey when combined with vitamin D during two metabolism periods in one of which honey is fed and in the other, Karo corn syrup.

That there are likewise differences in the conditions of different children affecting the degree of assimilability of calcium rendering a comparison between the results obtained with two individual subjects at one time inaccurate and inconclusive.

That the method of averaging employed in the instant case is the proper and accurate manner of determining comparative results of the two combinations.

That honey and vitamin D might be fed to the infants separately to obtain similar results to those obtained by the tests made provided that the honey and vitamin D were both active in the infant's body at the same time, in which event the combination would be formed within the body rather than prior to the feeding.

146 That it is the combination of honey and vitamin D which causes an increase in the calcium retained rather than the additive qualities of the two ingredients

separately, this conclusion being based on the comparison of the two carbohydrates used.

Further deponent sayeth not.

FREDERIC W. SCHLUTZ

Subscribed and sworn to before me this 24th day of July, 1939.

GEANE HOWELL
(Seal) *Notary Public*

My Commission Expires May 18, 1942.

* * * * * * * * * *

152 Endorsed: Mailed Aug 11 1939

MWL:RS Paper No. 10

Department of Commerce
U. S. Patent Office
Washington, D. C.

Before the Board of Appeals on Appeal

In re application of

Walter F. Straub
Serial No. 141,439
Filed May 8, 1937
Food Product

Examiner's Statement

This is an appeal from the rejection of all the claims, 1 to 5, 8, and 10, inclusive, reproduced below:

1. A food product comprising honey and vitamin D.

2. A food product comprising honey and a vitamin D concentrate.

3. A food product comprising a solution of honey and a vitamin D concentrate in the form of an alcoholic extract.

4. A food product containing honey and an oil concentrate of vitamin D emulsified in the honey.

5. A food product containing honey and finely divided crystals of vitamin D dispersed therein.

8. A food product comprising honey and vitamin D concentrated in a base immiscible with water, said concentrate being dispersed throughout the honey.

10. A food product comprising honey and concentrate containing vitamin D, said concentrate being soluble in honey.

153 Claims 4 and 5 are to non-elected species which have been retained pending the consideration of the generic claims. Claims 4 and 5, accordingly, stand rejected on the ground of estoppel to prosecute, in view of the voluntary election not to prosecute these species.

The art relied upon is:

Steenbock, 1,680,818, Aug. 14, 1928; Rasky, 1,892,902, Jan. 3, 1933; Crane, 1,911,882, May 30, 1933; Bresnick, 2,007,108, July 2, 1935; Hall, 2,022,464, Nov. 26, 1935; Hooper, 2,030,792, Feb. 11, 1936.

This application relates to a food product containing honey and vitamin D. The product is stated in the specification to be useful for stimulating or "normalizing" calcium metabolism in the body. The vitamin D may be added to the honey in any suitable form, although applicant prefers to employ a vitamin D concentrate in the form of an alcoholic extract. Such a concentrate mixes readily with honey. However, oily concentrates of the vitamin may also be used. Crystals of the vitamin are capable of being added to the honey.

A specific embodiment of the composition is shown by applicant to be one ounce of honey containing 100 U. S. P. XI units of vitamin D.

The Claims

Claim 1 broadly sets forth a food product comprising honey and vitamin D.

Claim 2 specifies that the vitamin is present as a concentrate.

Claim 3 specifies that the concentrate is in the form of an alcoholic extract.

154 Claims 4 and 5 use oil concentrates and crystals respectively.

Claim 8 is more specific than claim 2 in that the concentrate has a base immiscible with water.

Claim 10 specifies that the concentrate is soluble in honey.

The Rejection

All the active claims (1, 2, 3, 8, and 10) have been rejected as aggregative, since it does not appear that the honey and vitamin D coact or cooperate in any unusual or unexpected manner. Vitamin D has a well recognized function of controlling calcium metabolism. It is the outstanding agent in this respect for preventing rickets. In applicant's composition the vitamin appears to function only in its known capacity; and the honey, seemingly, supplies only its individual values.

Applicant has presented considerable argument accompanied by affidavits bearing upon the alleged coaction of the honey and vitamin D. However, after a careful study of the date submitted in the affidavits as well as the arguments presented therewith, the Examiner fails to find any data which supports applicant's conclusions.

An affidavit of Walter F. Straub, paper No. 3, relates to the feeding of infants with vitamin D and corn sugar and with vitamin D and honey. Straub concluded that with corn sugar the vitamin D definitely increased calcium retention in measurable amounts. He also concluded that with honey, the action of vitamin D is "enhanced". However, the affidavit gives no data as a basis for the conclusions, nor is there any definite significance attached to "enhancement" as used in the affidavit.

In paper No. 5, F. W. Schlutz presents an affidavit of a
character similar to the Straub affidavit. Feeding
155 tests were performed on infants, using corn syrup
and honey as carriers for vitamin D. Schlutz concluded that honey was a better carrier. That affidavit, like the one of Straub, gives no experimental data upon which conclusions can be based. Moreover, it is significant to note

that in four of the six infants tested by Schlutz, calcium retention obtained with syrup was higher than that with honey. Moreover, the affidavit does not establish that the results obtained with honey are any different from results which could be obtained by feeding honey and the vitamin separately.

The results of the first Schlutz affidavit in which syrup appeared to be a better carrier than honey were called to the attention of the applicant. Accordingly, a second affidavit was filed by Schlutz (Paper No. 7) in which the results are explained as follows:

> "That there are variable human idiosyncrasies and conditions in each individual child which affect the amount of calcium which will be retained by that child at any given time regardless of the combination fed. In other words, that the condition of the child at a particular time is a factor affecting the amount of calcium which will be retained regardless of the combination fed.
>
> "That it is impossible to compile comparative data by feeding both combinations at the same time and that it is improbable that identical conditions would exist in a particular child during two separate metabolism periods as regards these variable idiosyncrasies.
>
> "That there are likewise differences in the conditions of different children affecting the degree of assimilability of calcium rendering a comparison between the results obtained with two individual subjects at one time inaccurate and inconclusive."

However, in the first Schlutz affidavit, there is a positive allegation to the effect that:

156 "That the experiments were carefully controlled and supervised under uniform operating conditions and on the same group of infants throughout to obviate any misleading results due to biological variances in different individuals or due to inconsistencies or discrepancies in operating conditions."

That such control is virtually impossible is attested to in the portions quoted from the second and later Schlutz affidavit. Moreover, the individual tests indicate, seemingly, that in the majority of cases there was no unexpected or unusual coaction between honey and vitamin D. None of the affidavits has established that the results using vitamin D and honey in combination are any different from results obtained by using the substances separately. Applicant's responses have not even considered this aspect of the rejection.

Claims 1, 2, 3, 8, and 10 have been further rejected as lacking invention over the art cited above. The patents disclose food compositions in which honey and vitamin D appear as ingredients. Rasky and Crane disclose honey in food products. There is thought to be no invention in adding vitamin D for its known values.

Steenbock discloses that foods may have antirachitic properties imparted to them by the addition of vitamin D. Moreover, Bresnick specifically discloses honey in a vitamin D preparation. (See page 2, column 2, line 9 of Bresnick).

Claim 3 specifies that the vitamin is in an alcoholic extract. It is common to use alcohol as an organic extracting agent. The alcohol is known to be miscible with water. Hooper, moreover, discloses the use of various alcohols as solvents for vitamin D. The use of an immiscible base (claim 8) is shown by Hall.

157 It is apparent that the references show the use of honey, vitamin D, and suitable solvents used in food materials to obtain the healthful and useful functions of these substances. Bresnick clearly discloses the association of honey and a vitamin D material.

The rejection of the claims is thought to be sound and proper.

Respectfully submitted,

J. ISAACS
Acting Examiner, Div. 63.

158 Mail Division Aug 14 1939 U. S. Patent Office

Endorsed: Paper No. 12 Aug 15 1939 Division 63

Endorsed: Docket Division Aug 22 1939 U. S. Patent Office

Endorsed: Board of Appeals Aug 22 1939 U. S. Patent Office

In the United States Patent Office

Walter F. Straub,
Food Product,
Serial No. 141,439,
Filed May 8, 1937.

Div. 63
Room 4888

Affidavit

STATE OF ILLINOIS,
County of Cook, ss:

F. W. Schlutz, M.D., of lawful age, being duly sworn deposes and says:

That he is a citizen of the United States, residing in the City of Chicago, County of Cook, and State of Illinois;

That he is the deponent of the affidavits filed in the above-entitled case and sworn to on November 3, 1938 and July 24, 1939;

That he supervised the making of a series of tests, the results of which are shown on the chart attached hereto and marked Exhibit A and forming a part of the present affidavit;

That said tests cover a series of five-day metabolism periods preceded by five-day preparatory periods, as described in his affidavit of November 3, 1938, and that the measurements of the various materials involved and
159 the manner of feeding were the same as stated in said affidavit of November 3, 1938;

That the tests, results of which are shown on the accompanying chart, were made on two infants, referred to as

Guy and Geoffery, at a time when their ages ran from two to five months;

That six tests were made on each of the above-mentioned infants, each test comprising a five-day metabolism period preceded by a preparatory period, in three of which five-day periods corn syrup was included in the diet and in the other three of which five-day periods honey was utilized to contrast the effect thereof with the effect of said corn syrup, thereby giving three paired periods for each infant;

That for the first paired periods for each infant, cod liver oil containing 170 International units of vitamin D was included in the diet per day, that for the second paired periods of each infant, cod liver oil containing 340 International units of vitamin D was included in the diet per day, and that for the third paired periods of each infant, a vitamin product commercially known as Drisdol contain-
160 ing 500 International units of vitamin D was included in the diet per day;

That approximately 300 International units of vitamin D per day is usually considered as the normal requirement of an infant at the age of the two above-mentioned infants, and that therefore the 170 International units of vitamin D in the cod liver oil per day is substantially less than what is considered as the normal requirement, and that the 500 International units per day is substantially more than what is considered as the normal requirement;

That the accompanying chart shows, for the above-mentioned paired periods, the miligrams of calcium retained per kilogram of body weight per day averaged from the amounts retained during the respective five-day metabolis periods, and that for each set of paired periods the calcium retention when honey was included in the diet was substantially higher than the calcium retention when corn syrup was included in the diet;

That, as shown by these tests, for both infants the effect of the combination of honey and vitamin D on the calcium retention is most noticeable when the quantity of vitamin D is less than what is usually considered as the normal requirement;

161 That the results shown in the accompanying chart and referred to herein were obtained and calculated from tests just recently concluded.

Further deponent sayeth not.

FREDERIC W. SCHLUTZ

Subscribed and sworn to before me this 10th day of August, 1939.

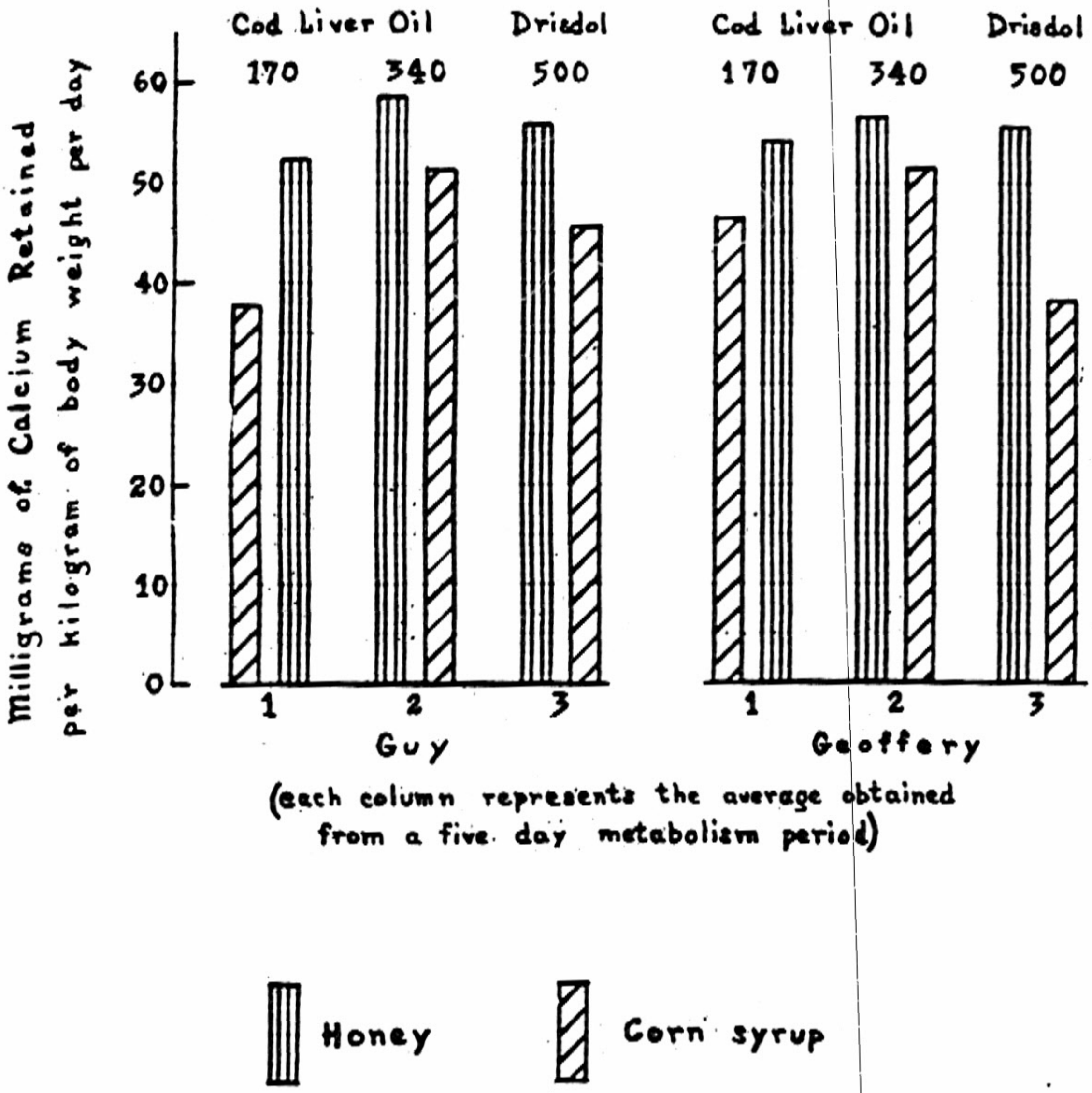
CAROLYN M. HENNING
Notary Public.

My commission expires June 18, 1941.
(Seal)

* * * * * * * * * *

The Effect of Honey upon Calcium Retentions When given in combination with different amounts and different sources of Vitamin D

(based on three consecutive paired periods,
contrasting honey with corn syrup,
for each of two infants age 2 to 5 months)



(each column represents the average obtained from a five day metabolism period)

Exhibit A

163 Endorsed: Mail Division Aug 14 1939 U. S. Patent Office

Endorsed: Paper No. 12 Aug 15 1939 Division 63

Endorsed: Docket Division Aug 22 1939 U. S. Patent Office

Endorsed: Board of Appeals Aug 22 1939 U. S. Patent Office

Supplemental Amendment

August 11, 1939.

Walter F. Straub,
Food Product,
Serial No. 141,439,
Filed May 8, 1937.

Div. 63,
Room 4888.

Hon. Commissioner of Patents,
Washington, D. C.

Sir:

Applicant files herewith an affidavit executed August 10, 1939 by Dr. F. W. Schlutz who executed the previous affidavits filed in this case. Entry of this affidavit is respectfully requested. It is regretted that the affidavit could not be placed on file before this, but the results of the tests covered therein were just recently obtained, and the affidavit was drawn promptly upon receipt of such results. The affidavit includes a statement to this effect.

The tests discussed in the affidavit in their broad aspect fully confirm the results obtained in previous tests discussed in the prior affidavits. These new tests further show the beneficial effect of the combination of honey and vitamin D when different amounts of vitamin D were included 164 in the diet. These tests show and particularly emphasize the very definite result of the combination of honey and vitamin D when less than what is considered as a normal amount of vitamin D is included in the diet.

There is nothing in any reference cited by the Examiner to show that honey alone has any effect on calcium retention. These tests show that there is a definite increase of calcium retention when honey and vitamin D are combined. It is therefore respectfully submitted that there is no basis for saying that the results obtained are due merely to the additive effect of honey and vitamin D taken separately.

It is respectfully requested that the enclosed affidavit be made of record in the case and be considered by the Examiner in the preparation of his statement on appeal.

Signed at Chicago, in the County of Cook, and State of Illinois, this 11th day of August, 1939.

WALTER F. STRAUB
By PARKER, CARLSON, PITZNER &
HUBBARD
Attorneys of Record.

10/10

165 Endorsed: U. S. Patent Office Board of Appeals
Aug 23 1939 Mailed

Appeal No. 32,151 OB

In the United States Patent Office

Before the Board of Appeals

Ex parte Walter F. Straub

Application for Patent filed May 8, 1937, Serial No. 141,439. Food Product.

Messrs. Parker, Carlson, Pitzner & Hubbard for applicant.

An affidavit having been filed in this case since the appeal was taken, the application is hereby remanded to the Primary Examiner, under the provisions of Rule 138, for reconsideration under the provisions of Rule 76 and for report to the Board of Appeals as to his conclusions thereon.

BOARD OF APPEALS

EUGENE LANDERS
Examiner-in-Chief

August 23, 1939

MESSRS. PARKER, CARLSON,
PITZNER & HUBBARD
28th Floor
1 N. La Salle St.
Chicago, Illinois

166 Endorsed: Mailed Aug 28 1939

MWL/hm Paper No. 14

Department of Commerce
U. S. Patent Office
Washington, D. C.

Before the Board of Appeals on Appeal

In re application of

Walter F. Straub
Serial No. 141,439
Filed May 8, 1937
For Food Product

Examiner's Statement
Under Rule 138

There has been presented an affidavit by Dr. F. W. Schlutz who executed previous affidavits filed in this case (Papers Nos. 5 and 7).

The present affidavit covers tests made on two infants over five day periods, using vitamin D with corn syrup and vitamin D with honey as test materials. Three different potencies of vitamin D were used, namely, 170, 340 and 500.

The results of the tests appear in Exhibit A attached to the affidavit. According to the exhibit, and the conclusions reached by the affiant, with each vitamin D potency, a greater calcium retention was obtained using honey.

It is noted that the difference at the normal vitamin D
level (340) is not substantial. In the case of infant
167 Guy, the difference is about 7 milligrams, and in the
case of infant Geoffery, the difference is about 5
milligrams. These differences, appearing in tests on two isolated infants, may well be due to favorable responses exhibited by Guy and Geoffery. The results do not appear to establish any general conclusions applicable to all persons. This is apparent, moreover, from the tests previously carried out by affiant, and discussed in the Examiner's Statement, Paper No. 10.

As shown in the previous Statement, affiant has (in Paper No. 7) pointed out various "idiosyncracies" and individual conditions which affect the amount of calcium retention regardless of the combination fed. The slight differences exhibited in the present tests on two responsive infants are well within the limits of the variations admitted by affiant to be possible in the tests.

Moreover, it is significant to point out again that the affidavit, like those previously presented, fails to establish that the results obtained with honey and vitamin D in combination are any different from results which could be obtained by feeding honey and the vitamin separately.

For the reasons given above, it is submitted that the affidavit presents no argument persuasive of any error in the rejection of the appealed claims for the reasons set forth in the Examiner's Statement.

Respectfully submitted,

A H WINKELSTEIN
Examiner, Div. 63.

168 Endorsed: U. S. Patent Office Board of Appeals Feb 21 1940 Mailed

Appeal No. 32,151 RHJ

Hearing:
February 8, 1940

In the United States Patent Office

Before the Board of Appeals

Ex parte Walter F. Straub

Application for Patent filed May 8, 1937, Serial No. 141,439. Food Product.

Messrs. Parker, Carlson, Pitzner & Hubbard for applicant.

This is an appeal from the action of the Primary Examiner finally rejecting claims 1 to 5, 8 and 10.

Claim 1 is representative of the subject matter involved.

1. A food product comprising honey and vitamin D.

The references relied upon by the examiner are:

Steenbock, 1,680,818, Aug. 14, 1928,
Rasky, 1,892,902, Jan. 3, 1933,
Crane, 1,911,882, May 30, 1933,
Bresnick, 2,007,108, July 2, 1935,
Hall, 2,022,464, Nov. 26, 1935,
Hooper 2,030,792, Feb. 11, 1936.

The above-copied claim sets forth the composition involved in this appeal. Evidence has been introduced into the record to show that the employment of honey with vitamin D will cause a greater amount of calcium to be retained in the system than will corn syrup in connection with vitamin D.

169 The examiner appears to imply that honey alone would increase the amount of calcium retained, but he offers no proof of this.

The examiner is also of the opinion that the tests shown in the affidavits are not sufficiently decisive and after careful consideration of them, we are of the opinion that the examiner was justified in reaching this conclusion. Undoubtedly, great care should be exercised in granting patents of a medicinal nature unless it be clearly established that the matter claimed can be relied upon to function in the manner stated.

Even if the proof offered were of such a character as to establish a material advance, there is the question as to whether the claims substantially distinguish over the patent to Bresnick. This patent discloses honey added to fish-liver oils. The only argument advanced by appellant against this reference is that it relates to a medicine rather than a food. It is believed that appellant's composition should be regarded primarily as a medicine and we note, in the last line of column 2, page 2 of Bresnick, that his product is in the nature of a confection. We do not consider that there is a patentable difference between the product of this patent and that of appellant with respect to the ground urged by him.

The decision of the examiner is affirmed.

BOARD OF APPEALS

EUGENE LANDERS
Examiner-in-Chief

February 21, 1940

W. L. THURBER
Examiner-in-Chief

F. J. PORTER
Examiner-in-Chief

PARKER, CARLSON,
PITZNER & HUBBARD
1 N. La Salle St.
Chicago, Illinois

* * * * * * * * * *

86 Filed Dec 18 1941 Charles E. Stewart, Clerk

In the Dist. Ct. of U. S. for Dist. of Col.

No. 8069 Civil Action

STRAUB

v.

COE

Memorandum.

Judgment for Deft. Notify Counsel

DANIEL W. O'DONOGHUE
Justice

Dec. 18-1941

* * * * * * * * * *

87 *Findings of Fact*

1. This is a suit brought under the provisions of Section 4915 R. S. (U. S. C., Title 35, Section 63) in which it was sought to have the Court find that plaintiffs, Walter F. Straub and W. F. Straub & Company, as the applicant and assignee, respectively, of application Serial No. 141,439, filed May 8, 1937, are entitled to the granting upon said application of a patent containing the claims set forth in paragraph 8 of the complaint, said claims being claims 1, 2, 3, 4, 5, 8, and 10 of the aforesaid application.

2. The said application of Straub is drawn to a food product comprising honey and vitamin D, which, it is alleged, will stimulate or normalize calcium metabolism in the body in order to insure proper bone formation and growth, and cure rachitic bone. According to his specification, Straub preferably adds to honey a vitamin D concentrate in the form of an alcoholic extract, with which extract the honey is said to be readily miscible. However, Straub states that he also may add to honey an oil concentrate of vitamin D emulsified in the honey, and that likewise 88 he may add and disperse in the honey finely divided crystals of vitamin D.

3. The three species of Straub's alleged invention, involving the addition to honey of (1) a vitamin D concentrate in the form of an alcoholic extract, (2) an oil concentrate of vitamin D emulsified in the honey, and (3) finely divided crystals of vitamin D dispersed therein, are claimed in (1) Claims 3 and 10, (2) Claims 4 and 8, and (3) Claim 5, of the Straub application, Serial No. 141,439, here in suit. Claims 1 and 2 of that application and here in suit are generic claims and read on all three species.

4. The plaintiffs have elected to prosecute claims to that species of invention defined by claims 3 and 10, and under the provisions of Rule 41 of the Rules of Practice in the United States Patent Office are not entitled to the allowance of claims 4, 5, and 8 of the Straub application, Serial No. 141,439, in suit, in the absence of a holding that generic claims 1 and 2 are patentable.

5. Steenbock in his patent No. 1,680,818, granted August 14, 1928, teaches that foods may have the antirachitic factor imparted to them by the addition of vitamin D, whose function is to preserve the normal deposition of calcium salts in the bones, thus preventing rachitis. Steenbock treats foods by ultra violet rays to render them anti-rachitic. Improved growth and proper formation of bone, Steenbock states, occur concurrently as the result of such activation of the foods. He recites that, in a slight degree, butter naturally contains vitamin D.

6. The patent to Rasky, No. 1,892,902, granted January 3, 1933, discloses a food product comprising an admixture of honey and butter.

89 7. The patent to Crane, No. 1,911,882, granted May 30, 1933, discloses a food product comprising honey and apricots.

8. The patent to Bresnick, No. 2,007,108, granted July 2, 1935, discloses a medicinal preparation containing fish-liver oils of high vitamin D content, in which the objectionable odor and taste of these oils are masked. This preparation is a solid in the nature of a confection, and, in one practical

form, may be produced by a mixing of 35-40% vegetable fat, such as cocoa butter, 15% flavoring, 40% sweetening, and 10-5% fish-liver oils. Bresnick recites that grain honey is a satisfactory flavoring.

9. The patent to Hall, No. 2,022,464, granted November 26, 1935, discloses the emulsification of vitamin D concentrates having an oil base and the incorporation thereof in food products.

10. The patent to Hooper, No. 2,030,792, granted February 11, 1936, discloses the solution of vitamin D in various polyhydric alcohols to give vitamin D concentrates in the form of alcoholic extracts.

11. Plaintiffs have not established that honey and vitamin D coact or cooperate in any unusual or unexpected manner, and particularly have not proved that the result obtained from feeding a mixture of vitamin D and honey are more than the additive effect obtainable by feeding honey and vitamin D separately.

12. It was not invention to add vitamin D to honey or to a food product containing honey, and it particularly was not invention to add a vitamin D concentrate to honey or to a
food product containing honey, whether it be a vita-
90 min D concentrate in the form of an alcoholic extract,
or an oil concentrate of vitamin D emulsified in the honey, or finely divided crystals of vitamin D dispersed in the honey.

13. If the mixture of vitamin D and honey disclosed by the patent to Bresnick, No. 2,007,108, or the mixture of honey and butter containing vitamin D disclosed in the patent to Rasky, No. 1,892,902, when used as a food would have an effect upon calcium retention in the human body, the discovery of that fact would not be an invention.

Conclusions of Law

1. Claims 1 and 2 of the Straub application, Serial No. 141,439, are either anticipated by the patent to Bresnick, No. 2,007,108, or unpatentable thereover; and claim 1 also

is either anticipated by the patent to Rasky, No. 1,892,902, or unpatentable thereover.

2. Claims 1, 2, 3, 4, 5, 8, and 10 of the Straub application, Serial No. 141,439, are not patentable over the patents to Steenbock, No. 1,680,818, Rasky No. 1,892,902, and Crane, No. 1,911,882 particularly in view of the patents to Hall, No. 2,022,464, and Hooper, No. 2,030,792.

3. Claims 1, 2, 3, 4, 5, 8, and 10 of the Straub application, Serial No. 141,439, express a mere aggregation rather than a patentable combination.

4. Plaintiffs are not entitled to the grant of a patent containing any of the claims 1, 2, 3, 4, 5, 8 and 10 of the Straub application, Serial No. 141,439, here in suit.

5. The complaint should be dismissed as to all the claims in suit.

DANIEL W. O'DONOGHUE
Justice.

Jany. 26 - 1942

* * * * * * * * * *

91 *Judgment*

This action came on to be heard at this term; and thereupon upon consideration thereof, it is, this 26th day of January, 1942, adjudged that the complaint be, and it is hereby dismissed with costs against the plaintiff.

DANIEL W. O'DONOGHUE
Justice.

* * * * * * * * * *

92 *Notice of Appeal*

Notice is hereby given that Walter F. Straub and W. F. Straub & Company, plaintiffs above named, hereby appeal to the United States Court of Appeals for the District of Columbia from the final judgment of the above-entitled court entered in this action on the 26th day of January, 1942.

Dated this 24th day of February, 1942.

THEODORE A. HOSTETLER
Attorney for Plaintiffs
National Press Building
Washington, D. C.

Of Counsel:

PARKER, CARLSON, PITZNER & HUBBARD
LOWELL C. NOYES
1 North La Salle Street
Chicago, Illinois

Copy received this 24th day of February, 1942.

CONWAY P. COE,
Commissioner of Patents

By W. W. COCHRAN
Solicitor

* * * * * * * * * *

TESTIMONY.

10 In the District Court of the United States
For the District of Columbia

Civil Action No. 8,069

WALTER F. STRAUB and W. F. STRAUB & COMPANY, *Plaintiffs,*

v.

CONWAY P. COE, Commissioner of Patents, *Defendant.*

Washington, D. C.,
Wednesday, December 10, 1941.

The above-entitled cause came on for hearing at 11 o'clock a. m., before Honorable Daniel W. O'Donoghue, one of the Justices of said Court.

Appearances:
Theodore A. Hostetler, Esquire, and
Lowell C. Noyes, Esquire, for the plaintiffs.
Clarence W. Moore, Esquire, for the defendant.

Proceedings

The Court: You may proceed.

Mr. Hostetler: Your Honor, this is a suit under Section 4915, in which we are asking the Court to authorize the issuance of a patent which was refused by the Patent Office, erroneously as we believe.

11 The inventor, Walter F. Straub, is a man from Illinois; and Mr. Lowell C. Noyes, my associate here, also from Illinois, prosecuted the application in the Patent Office and he is a member of the bar of the highest court in his State of Illinois—and so am I. He is not a member of the bar of this court. Therefore I move or request that he be admitted for the purposes of this suit.

The Court: Very well.

Mr. Hostetler: I thank you.

Opening Statement on Behalf of Plaintiffs

Mr. Hostetler: Your Honor, probably we have had very few patent cases that are so clear and so easy to understand as the one that we have here today.

We know that the growing human body needs a great deal of calcium. In children, and especially infants, a lack of calcium, an insufficient amount of calcium, of course, results in rickets, a disease which was not understood years ago. However, quite a while since they discovered that vitamin D would facilitate the assimilation of calcium, if supplied with food that contains the calcium.

For illustration, milk is very rich in calcium; and when this vitamin D is fed with milk or with any other food that has calcium in it, the vitamin D facilitates the assimilation of the calcium by the body—the bones and teeth and
12 other parts of the body—and as a rule the body

would absorb some of the calcium; but the vitamin D greatly facilitates that absorption.

Now, to get right down to the point, Mr. Straub's contribution to the art, the advance that he makes over this common knowledge that vitamin D facilitates the absorption and the assimilation of calcium, was in the discovery that honey had the characteristic of enhancing it or making it more effective; that when the food product of honey combined with vitamin D was fed with the other foods the result was decided increase in the assimilation of calcium.

Now, we presented in the Patent Office tests, reports of tests, which the Patent Office did not regard as sufficient; and we want to augment those.

We have here two witnesses who have made these tests, numerous tests; and we want to establish that this characteristic of honey is effective in facilitating the assimilation of calcium.

Now, certain prior art was cited here, which is found in six patents, which are included in the folder which the Solicitor will present as defendant's exhibit.

Candidly, I do not think that any of these references have anything at all to do with the case, unless it is to show that we have an invention here that is patentable. Your Honor will observe that there are only three of those
13 references that mention honey at all.

Take for illustration the Crane patent 1,911,882. Well, let's see what that is. This patent is for "Food Product." In the third paragraph of the specification he says:

> "I combine apricot and in a dried or dehydrated form with honey in granulated form."

And he says:

> "The product by reason of the presence of the apricot does not have the stickiness and fluidity of honey, and, therefore, the product is convenient to handle, especially when used as a spread because it does not tend to run and

yet it may be readily spread or applied to the surface of a slice of bread for example.''

That is found at line 27 on the first page; and that is all there is to that patent, that matter of convenience. We know how difficult it is to spread honey. It is sticky. No matter how careful you are at the table, if you handle a dish that has honey in it you are bound to get honey on various things.

That is all there is to that patent and there is nothing in there about utilizing that honey to enhance the absorption or assimilation of calcium; and there is no mention of any vitamin at all in there. It is merely the mixture and it is something that is given to the public for its convenience;
and he is probably entitled to that under the constitutional
14 provision that provides for patents.

Then we have, as another one, the Rasky patent 1,892,902, granted in 1933. He makes a mixture of butter and honey and sells it—just as he would butter. The mixture is used as a spread. Now, that depends on the temperature. At room temperature, of course, it is a solid. If it gets warmer than ordinary room temperature the honey and butter spread would become plastic; and if it is warm enough it would become a liquid.

On page 1, line 27, he says:

> ''My product consists only of honey and butter, and the term honey is used to include natural bees' honey, or a product artificially prepared as a substitute therefor; and similarly the term butter is used to include butter and butter substitutes such as are common on the market.''

Now, at some place in the record, at the beginning of the prosecution, the examiner in the Patent Office referred to butter as containing vitamin. However, the vitamin is in such a small proportion that it would be absolutely negligible as a means for facilitating the absorption or the assimilation of calcium; and all that inventor had in mind was a convenient mixture that the housewife could use as a spread.

Now, all of these references appear to have been dropped
by the Board of Appeals. They refer only to one
15 and that is the Bresnick patent number 2,007,108.

Now, Bresnick has fish oil; and fish oil has such a disagreeable odor and taste that they have to flavor it or get rid of that terrible taste. Now, near the bottom of page 2, column 1, line 50, Bresnick says:

> "Although the combining of the vegetable fat in the form of cocoa butter with the fish-liver oils in such a manner that the composition is substantially anhydrous, whereby the fish-liver oils are effectively preserved against deterioration, results in a useful product, the full utility thereof as a medicinal preparation is not realized until one or more masking ingredients are added to hide the objectionable taste and odor of the fish-liver oils."

Your Honor will note that he combines fish liver oils with cocoa butter as a base.

Now, following right along there, he mentions a number of things. In the last paragraph on page 2, column 1, he says:

> "Any desired flavoring may be employed, preference being shown to flavorings having the least moisture and which in themselves are fairly stable, such as spices, barks, powdered and essential flavorings. Cocoa and a terpeneless orange oil in combination are excellent as flavorings."

And he goes on to name various other things that
16 may be incorporated; but at the end of the paragraph,
at the top of column 2 on page 2 I read one sentence
"I have found grain honey a satisfactory flavoring."

Now, it is not necessary to discuss the other patent, Steenbock, 1,680,818. Steenbock, of course, is an authority on the vitamins; and he discusses the way that various vitamins are used and, you might say, developed, some of them by ultra violet rays, either artificial or natural from the sun.

Now, our contribution, as I said, is just confined to the use of that one vitamin D, which in itself facilitates the absorption or assimilation of calcium, and the combination with honey. When the two together, the honey and the vitamin D, are combined to form this product, it enhances the power of that vitamin D to facilitate the absorption of the calcium.

Opening Statement on Behalf of Defendant

Mr. Moore: There is one technical question involved here that might be disposed of before I go into the merits of the case.

Claims 4 and 5 are species claims. Claim 3 is also a species claim. The remaining claims are generic claims.

Under the rules of the Patent Office the applicant was required, since the generic claims were rejected, to elect one of the three species claims; and he elected claim 3 and retained claims 4 and 5 merely for the purposes of appeal, it 17 being understood that should the generic claims ever be allowed to the applicant, he would then be entitled to claims 4 and 5; but in no case could the applicant be allowed claims 4 and 5 without the allowance of one or more generic claims, that is, the allowance of claims 1, 2, 3, or 10.

Now, as your Honor will perhaps notice, these claims are very broad.

Claim 1 calls for:

"A food product comprising honey and vitamin D."

Claim 2 specifies that vitamin D is present as a concentrate.

Claim 3 specifies that the vitamin D concentrate is in the form of an alcoholic extract.

Claims 4 and 5 specify an oil concentrate of vitamin D and finely divided crystals of vitamin D.

Claim 8 refers to vitamin D concentrated in a base immiscible with water.

Claim 10 refers to concentrate containing vitamin D, said concentrate being soluble in honey.

There were two broad grounds of rejection by the Patent Office.

The first was that the food product comprising honey
and vitamin D was merely an aggregation and that in that
food product the honey serves its usual functions and the
vitamin D serves its usual function; that there is no
18 cooperative result, unusual and unexpected, that
comes from the combination of the two.

The second broad rejection was on the art, the patents that were cited in the examiner's statement.

The Board did refer specifically only to the Bresnick patent; but the Board did make a general affirmance of the examiner's final rejection; and, in any event, all of the patents cited by the examiner are here, by reason of having been cited in the answer of the Commissioner of Patents.

The patent to Steenbock, of course, is the well known patent that concerns the irradiation of foods to impart vitamin D to them; and is a broad general discovery. As stated in the first paragraph of that patent, the invention relates to a method of preparing antirachitic products of edible character, such as foods and medicines, and to the products obtained by such method of treatment.

The patent says, on page 3, line 78 and following:

"It has been found, also, that improved growth and proper formation of bone occur concurrently as the result of activation of the food in the manner herein described."

The patent to Rasky is cited because it concerns a food
product comprising honey and butter. The butter is stated
in the examiner's statement to contain vitamin D; and that
is corroborated by statements in the Steenbock patent that
vitamin D would in any case be contained in butter.

19 The Crane patent has merit only in that it specifies
that a food product is made that contains honey.

The patent to Bresnick, and particularly page 3, column 1, line 22 and following, says:

"A highly practical composition is formed by a mixture of 35-40 per cent vegetable fat such as cocoa butter, 15 per cent flavoring, 40 per cent sweetening and 10-5 per cent fish-liver oils."

That is a medicinal preparation or vitamin product that Bresnick discloses; and, as Mr. Hostetler pointed out, Bresnick, on page 2, in the second column, lines 9 and 10, says that grain honey may be the flavoring—the flavoring specified in the portion that I read from page 3 of that patent.

As I said earlier, some of the claims here call for an oil base, an oil concentrate. The Hall patent is important as specifying the use of an oil base with vitamin concentrates.

The Hooper patent, the last patent cited by the examiner, is important as stating that polyhydric alcohols generally can be used as the base of the concentrate.

We feel that these claims are quite broad and that the primary examiner and the Board properly refused them to the applicant.

Mr. Hostetler: You will notice, Mr. Moore, that the Board does not say anything about that question of aggregation.

I assume that they did not sustain the examiner on that question of aggregation. That is the reason I did not refer to it in my statement.

In the Board's decision, at the top of page 2, they say:

"The examiner appears to imply that honey alone would increase the amount of calcium retained, but he offers no proof of this."

I think we will find that in the whole record there was no reference that covers our invention at all, even remotely; and the record shows reference to various rejections that are simply dropped out, as indicated in the Board's decisions.

Mr. Noyes: May I call Dr. Schlutz as a witness?

The Court: Do you want to offer in evidence the file wrapper?

Mr. Hostetler: Oh, yes, your Honor.

I want to offer in evidence a certified copy of the file wrapper as Plaintiffs' Exhibit No. 1.

Mr. Moore: No objection.

(The document so produced and identified was received in evidence and marked Plaintiffs' Exhibit 1.)

Mr. Moore: Your Honor, may I, with the permission of Mr. Hostetler and Mr. Noyes, offer in evidence, out of order, the booklet which I have handed up to your Honor, so that it may be before the Court during the examination of the witness?

The Court: There being no objection, it is admitted as Defendant's Exhibit No. 1; and the one just offered
21 by Mr. Hostetler is admitted as Plaintiffs' Exhibit No. 1.

Mr. Moore: Defendant's Exhibit 1 is a folder consisting of copies of:

A—Steenbock patent 1,680,818
B—Rasky patent 1,892,902
C—Crane patent 1,911,882
D—Bresnick patent 2,007,108
E—Hall patent 2,022,464
F—Hooper patent 2,030,792
G—Examiner's Statement, August 11, 1939
H—Examiner's Statement, under Rule 138, August 28, 1939
I—Decision of the Board of Appeals.

(The folder so produced and identified was received in evidence and marked Defendant's Exhibit 1.)

Thereupon **Frederick W. Schlutz** was called as a witness for the plaintiffs and, being first duly sworn, was examined and testified as follows:

Direct Examination

By Mr. Noyes:

Q. 1. State your full name, Doctor. A. Frederick William Schlutz.

Q. 2. Will you please tell the Court your present
22 occupation? A. I am Professor of Pediatrics at the University of Chicago and am head of the department; and am at the present time a teacher of pediatrics and also a practitioner, because we have practice cases com-

ing there, of course, that I conduct at the university clinic. I also see private patients.

Q. 3. Will you please state your education and past experience? A. I graduated from the University of Maryland in 1902 and took two years of post graduate work in junior positions, as resident in the hospitals in Baltimore, and did some post graduate work at Johns Hopkins during that time.

And then I passed the Board in Minnesota and practiced medicine and was engaged in the general practice for about five years in the southern part of the state, and also in the iron range.

I went abroad in 1909, to take up the special study of pediatrics; and was at the Universities of Berlin, Kiel, Strassbourg, Paris, and London during that year.

Then I came back to Minneapolis and located there in the practice of this specialty of pediatrics; and I was at that time, from the beginning, connected with the University of Minnesota in junior capacities, as a teacher.

And, also, during my stay in Europe I studied biochem-
istry while there—that is all I was engaged in—that,
23 along with my pediatric studies.

I was instructor in biochemistry at the university for two years, and also instructor in pediatrics.

From 1912 to 1918 I was instructor in pediatrics at the university and rose to the rank of assistant professor; and at the same time I was taking graduate work in biochemistry at the university under the direction of Professor Foline, of Harvard, toward a Ph. D. degree in biochemistry.

In 1918 I went into the Army and was stationed at Camp Devens, Massachusetts, where I was assistant medical officer in charge of contagious diseases for the 52nd Division; and I was there until 1919; and, with the permission of the Government, was permitted to continue my work at Harvard University under Professor Foline.

I did not quite complete my work for the degree; and I had nine months to go to complete my work for the Ph. D. degree.

At that time the conditions at the university required that I return to the university and to my practice.

I might say that I was practicing pediatrics in Minneapolis during this entire time while I was at the university.

In 1923 I was appointed head of the Department of Pediatrics at the University of Minnesota, and gave up my private practice, only doing practice in connection 24 with my duties at the university.

All this time I was doing work in this field of biochemistry.

I was head of the department there from 1924 until 1930; and then I was called to the University of Chicago in the same capacity, as head of the children's department at the University of Chicago; and have been there since, as head of the department, and teaching.

During this time I myself, and people under me, have been engaged in research, mostly of a biochemical and physiological nature.

During the past seven or eight years we have particularly worked in the field of vitamin research and also on the physiology of fatigue. Those are the two principal fields in which we are at the moment doing research.

The laboratories of the University of Chicago are probably as finely equipped as any in the country. We have an adequate staff and we do feel that the work that is done there is of a very high order; and it is so recognized.

Q. 4. Now, will you tell the Court, please, generally, about the need for calcium in the body? A. Calcium is to the young growing organism, especially to the infant and the young child, one of the most important minerals in the whole system of minerals that the body needs.

The body needs calcium for the growth of bone 25 and muscle building primarily; but the element has other very extremely important functions, in other processes that deal with the general wellbeing of the body. For example, it is an absolutely essential element in the blood clotting mechanism; it is very important; and, if it is not present, we have very serious disorders, which may cause fatal bleeding.

It is an element of very great importance in the osmotic functions in the body.

It has very important functions in the nervous system, in the proper functioning of the nervous system.

In the very young child, in the infant, I think it is safe to say it is one of the most important elements in the whole body, except possibly iron.

In the adult it is less important, although of continued importance, for these various functions—not so much the bone and body building functions as the body gets older, because less of those are required then than are required by the infant. Its importance is particularly great in the very young infant.

Q. 5. Now, in connection with the assimilation of calcium by the body, vitamin D is the thing that increases that, is it not? A. That has been one of the great discoveries of recent times, that this vitamin has this important function, that it facilitates the absorption of cal-
26 cium, that it regulates the calcium metabolism in the
body—that is, the ratio in which these elements must be present in optimum amounts; and it has important functions in the regulation of the activity of the hormones. If such an element is not adequately present, that is, there is a very seriously deranged condition, then vitamin D is added in that important function.

Vitamin D is one of the very essential elements that we need—unfortunately not widely distributed in nature. It is a vitamin that is not very largely present in natural foods; but is, however, present in some of them.

Q. 6. Now, in connection with the invention with which we are here concerned, and with the use of honey and vitamin D, you have made a number of tests in connection with your work, to determine what value that has? A. Yes.

Q. 7. Will you describe those tests? A. Well, we had occasion to work with honey in connection with the study of various carbohydrates, their utilization in the body, the rapidity with which they were absorbed, and so on.

In this connection we made some very interesting observations on this carbohydrate, and they bore out the presumption which one could have, if he were familiar with the composition of the substance, being made up of two
natural sugars, both of which are, in themselves, most
27 acceptable to the human organism.

In the course of these studies and observations on the effect of honey, it has seemed to have an effect on the better calcium absorption; and it was suggested to us that it might be feasible to add vitamin D, which had such a known beneficial effect on calcium absorption, to this product.

Being interested in any nutritional phase of this thing, in the whole problem of nutrition, and in anything that would give favorable combinations, that would affect these favorable situations with reference to calcium absorption, for example, we took up the idea and carried on quite a series of experimental researches in this field; and with the result of some very interesting observations.

Q. 8. Will you please describe the method of making those tests and experiments and the time and all the elements concerned with them? A. Yes.

Tests of that sort are made by what we call, in the scientific parlance, balance studies, in which we measure exactly the amount of these substances in the intake, in the food that is consumed, and measure the amount that is excreted in urine and feces; and these are balanced; and what is left is looked upon as retention.

That has been proved and is, I think, the only method we
have of studying the effect of various nutritional sub-
28 stances on the body, particularly with reference to
mineral retention.

These balance studies are in the nature of metabolism studies—we call them.

The subject is placed on a bed; and at first he is prepared, after a preliminary period, and placed on a food which it is not intended to study, as a preliminary period, and during which time his organism supposedly gets in balance, as we call it, that is, the minerals and elements all get into a picture which is the true picture, without having had the element which we want to influence.

Then there is an actual metabolism experiment, in which the subject, usually an infant, is placed on a special type of bed, that permits an accurate quantitative collection of the feces and urine and accurate measurement of everything that is taken in.

These are all weighed accurately. For instance, if the infant vomits or spills, that is all accurately measured, so that we have an accurate picture of what is taken in and the mineral content, that is, the mineral intake is determined.

And then the actual quantities of feces and urine are also collected; and that gives us the picture of what we call a balance study.

Now, in this particular instance, of this particular research, we had as subjects 14 infants, over a period of about
five years. This study was extended over a period of
29 about five years. We have had 14 infants who have
been so studied; and on them we have had a total of
120 metabolism periods—many of the infants having as high as 10 and 12 periods.

I might say that when we have had such a period of study there is an intervening period when the infant is off the bed and allowed to get into this balance without having the substance that we want to study, for some weeks; and then again it is placed on the metabolism bed and then they have other such studies. Of some infants, I believe, they have had as many as 10 or 12 observations; and that gives us the total average of this type of examination, gives us, I believe, the true picture of what has really been going on. It is the accepted method of approach to that sort of a problem or study.

Q. 9. These actual periods then—your preparatory period continues about how long? And your test or metabolism period continues about how long? A. The premetabolism period averages, possibly, five to ten days. It varies. The actual metabolism period in our studies averages always five days; that is the accepted period or length of time that will give you accurate information.

Q. 10. Will you state what the reaction of the human body is to diets? Does it have a regular reaction or does
it vary? A. There is quite a bit of variance in the
30 requirements of the body, depending sometimes upon
various conditions. The mineral requirements in
some periods may be very high; and there may be a period of very active growth; and then there may be a period in which the demands are less.

There is quite a bit of individualism in a given case in that respect. It is a question of the body requirements at the moment. The body has a way of regulating that itself; and fitting that requirement to its needs.

Q. 11. What infants were these that you made the tests upon? A. We selected for this study only what we regarded as normal infants from The Evanston Cradle, which is a foundling institution in which infants are received, usually shortly after birth, two weeks or three weeks.

The infants we got from there were mostly around four or six weeks old when we took them. They were infants who were under exceptionally fine care. It is a well known institution, familiar to most of you, and these infants are all of them adopted out into families and have exceptionally fine care; and I have had a good deal to do with this institution myself and have first hand knowledge of it.

We had material which was in every way normal. We had infants that were normal. We were not taking the cases which come into the clinic, where we often have a very
poor class of material, in a very poor nutritional
31 state. We rejected such infants, and took only in-
fants in first class, normal condition for the study.

Q. 12. Will you state the period of the infant's life in which these tests were made? A. They were all made within the first six months of the infant's life.

There was a reason for that. The infant up to that age is so largely dependent upon milk for food—you might say for the first few months of his life entirely dependent; and it is also the period when the infant has the greatest need for these minerals, his greatest need for calcium and phosphorus is in that period.

It is also the period in which we can make the most significant determination, on account of the simplicity of all the factors. We have not a lot of extraneous variables introduced, which could distort the picture. It is for that reason that that is the period taken for these particular studies. It is the simplicity of the test. The food mixture is simple, is measurable, and can be quantitatively easily obtained; and the effect of any change or alteration is very striking in such cases—more so than in the older children.

Q. 13. You can say, however, that the results obtained with these infants would apply to older children and to adults? A. Oh, yes.

32 Q. 14. In a lesser degree? A. Oh, yes. There are studies of these things on older children and on adults. There are such studies; and the requirements of the body's needs have been determined in that way and are very well known; and it has been established that in that age, infancy, the need is very great; and that as the individual becomes older the needs are less and less than they are in the very young infant.

Q. 15. These tests that you have made on this particular subject matter ran over a period of about how long? A. Five years.

Q. 16. And how many children and how many tests did you make? A. Fourteen children altogether and 120 metabolism periods were studied during that time.

Q. 17. In any diet fed to children it is not possible, is it, to entirely eliminate vitamin D? A. Not entirely. There is a very small amount of vitamin D in milk, about in the neighborhood of four to forty units, a stretch of about between that figure, in a quart of milk. It is a very small amount; but there is that much present in the milk.

Q. 18. Now, in these tests that you have made, it is true, is it not, that individual tests can not be set up against others to determine the effect, but you must take the
33 averages? A. Yes. You have occasionally one single test that might show a high retention; it might show a very high retention; and another subject, with, for example, a period under other circumstances, might show a much higher retention with corn syrup, for example, than with honey.

There is an occasional case which might show in one period a high figure; but the only accepted way to judge of these actual effects is to take the total average of all the cases studied and base your deductions from that.

Q. 19. Now, as a result of these tests what are your conclusions as to the product we are now concerned with, composed of honey and the vitamin D? A. Well, we were quite surprised to find that honey with vitamin D associated with it gave consistently, in all of the tests and in comparison with other sugars and with changes of various types of milk, almost the same consistent effect, that there was a very substantial, a quite substantial, retention of calcium over what we got with other forms, where other substances were used than honey, for example corn syrup. We always found that result in all of the tests. That is true for the entire series that we had a more favorable retention of the calcium with the honey and D.

Q. 20. You stated that was the result of the various tests. Was that true with all the types of milk? A. Yes.
34 We used, for example, various types of milk. It is known, for example, that acid milks favor the retention of the calcium in themselves. For example, lactic acid milk, which is very widely used in pediatric practice today; and we used such milk and we used plain milk, evaporated milk, dried half-skim milk, processed milk.

With the use of such milks the effect still was a better one than if used alone or if some other sugar was used than honey; for example, corn syrup.

Q. 21. In these tests you also varied the amounts of vitamin D? A. Yes. We gave vitamin D at various levels. There were tests with no D added; there were tests with a moderate amount of D added; and there were other tests with a very high amount of vitamin D—500, 680, and even a thousand units. The reasons these amounts are used are that the accepted amount or requirement for the body lies between 400 and 1,000 units; and the Nutrition Commission recently appointed by the Government has fixed the amount at 800 units. We tried with all the various amounts to see what effect we would get and in all of them we had this better retention effect when we used the honey with vitamin D.

Q. 22. As to the theory of the action that takes place, can you advance any thoughts on that—as a result of these tests? A. I have the definite impression and I would be of the opinion that the favorable action is possibly mainly due to the fact that honey forms a vehicle or medium in which vitamin D acts well.

We do know, from earlier experimental work we did that the sugars in honey, the two natural sugars in honey, dextrose and fructose, are very acceptable to the body, and favorably received, readily absorbed—dextrose particularly and levulose almost equally so. Levulose has an added value, that it keeps a better level of blood sugar—both of which factors would incline us to believe that those are very acceptable sugars for use in the body; and that is one of the reasons why we have advocated, or are putting forward the suggestion, that honey be more widely used in infant feeding.

This rapid absorption may explain the favorable action of the D when associated with honey.

There is another possibility. There is in honey, unlike other sugars, a very small amount of organic acids. We do not know how much; there is a very small amount. It is known, however, that certain organic acids, citric acid and tartaric acid, also favor the absorption of vitamin D when present in the intestinal tract; and that the main item in the favorable action is the rapid and natural absorption of these two carbohydrates in the intestinal tract; and they form an exceptionally good vehicle for vitamin D, for carrying the D.

36 Q. 23. Can you discuss briefly the use of this product in the feeding of infants, from a practical standpoint? A. Well, honey is apparently a very suitable carbohydrate for infant feeding. It mixes very readily with the various milk mixtures and it is very palatable; and we have had no untoward effects with its use; and the infants are singularly free from diarrheal manifestations. They thrive, as evidenced by fine gain in weight. They are in every respect infants who do very well on the given form of milk plus this carbohydrate.

We have every reason to think that vitamin D added in this form would enhance that, would improve that situation, since D is used a good deal; I mean it is given in infant feeding, of course.

Q. 24. In view of this experimental work of yours, would you, as a pediatrician, prescribe this product for use in infant's diet? A. Without hesitation. What experience we have had with it, in the way of the results of the infant feeding, the infant's reaction to the product, has been only favorable and not in any way unfavorable; and we distinctly feel that it is in some instances better than the experiences we have had with other types of mixtures; and I think I can say that I would, without hesitation, prescribe that type of mixture if it were suitably prepared—assuming that that is possible.

37 Q. 25. Doctor, you have read, I believe, the Bresnick patent number 2,008,108, one of the patents cited as references in this case. A. Yes; I have.

Q. 26. And you have considered the product that Bresnick claims to have invented? A. Yes; I have.

Q. 27. Will you describe the nature of that product? Is it a predominantly oily product? A. I have not seen it, but I should think that it is, since it contains up to 40 per cent of cocoa butter, I believe, which is a fatty substance, a hard fat; and the vitamin which is added, I believe, is added in the form of oil concentrate; and the amount added is very small; I believe it is in the amount of five per cent to ten per cent, which would furnish in the total product a very small content of vitamin D, which, in the examples he gives, would be really very modest in its effect, I should think.

There is also, I believe, added to it, as a flavoring agent, up to 15 per cent of honey, which is again a very small addition of honey, with reference to the total mass.

Q. 28. Would this product be at all suitable for an infant's diet? A. Utterly not; it could not possibly be used; it would be harmful, I should say.

Q. 29. If an adult ate it, would he get much benefit
38 from the vitamin D that is contained in it—unless
he had large quantities? A. I should say not unless he consumed very large quantities of it. It is possible then that he might get some beneficial effect.

Q. 30. Does butter have any appreciable amount of vitamin D? A. A very small amount, about four—between four and fifteen units in a teaspoonful of butter, which is about the average pat that you consume as a portion.

Q. 31. Do apricots contain any appreciable amount of vitamin D? A. Practically none; none as far as I know; there is no vitamin D in apricots.

Mr. Noyes: That is all.

Cross Examination

By Mr. Moore:

X-Q. 32. Dr. Schlutz, you would recommend honey alone as an infant food? A. Yes; it has a good record, I think.

X-Q. 33. And also vitamin D, in one form or another, as an infant medication? A. We do give them separately; yes.

X-Q. 34. Now, you say that your tests with these infants, 14 infants, extended over a period of five years? A. Just about.

39 X-Q. 35. They began, then, about this time in 1936? A. Yes.

X-Q. 36. And you have studied 14 infants in that way? A. Fourteen, yes.

X-Q. 37. Now, you executed certain affidavits that were filed in the application of Straub, did you not? I will show you the affidavits (exhibiting Plaintiffs' Exhibit 1). A. It would be some time ago. I believe I did.

X-Q. 38. I show you an affidavit which has been marked paper number 5 in the application filed, that is, Plaintiffs' Exhibit No. 1. It is an affidavit executed the 3rd of November, 1938. That is your signature to that affidavit, is it not? A. Yes.

X-Q. 39. And that affidavit was accompanied by a chart, was it not? A. Yes.

X-Q. 40. And the affidavit refers to the chart? A. Yes.

X-Q. 41. And you subsequently prepared another affidavit, dated the 10th of August, 1939? A. Yes.

X-Q. 42. And you say that is your signature to that affidavit? A. Yes.

40 X-Q. 43. That is paper number 12 in this application of Walter F. Straub? A. Yes.

X-Q. 44. And that affidavit also is accompanied by charts? A. Yes.

X-Q. 45. In these charts that accompany that first affidavit there are mentions of Ned, Bart, Myles, and John. A. Yes.

X-Q. 46. Those are four of the 14 infants who were tested? A. That is right.

X-Q. 47. Now, those tests, as shown on the charts, were comparative tests, weren't they? A. Yes.

X-Q. 48. Now, those tests used Karo corn syrup combined with vitamin D in cod liver oil and honey combined with vitamin D in cod liver oil? A. Yes.

X-Q. 49. And in the case of infant Ned, for instance, shown in the first chart, the assimilation of the calcium in that case was greater in one instance with Karo corn syrup than it was when cod liver oil was used with honey, was it not? A. Yes.

X-Q. 50. And the same thing is true with infant Bart, is it not? A. Yes; that is.

41 X-Q. 51. And in one instance, at least, with infant Myles? A. Yes.

X-Q. 52. In fact, there were—in the case of the infant Myles there were several instances where the assimilation was greater with Karo corn syrup combined with vitamin D in cod liver oil than it was with honey combined with vitamin D in cod liver oil? A. May I—

X-Q. 53. (interposing) Just let me finish this question. A. Yes.

X-Q. 54. Then, with the infant John, there was also the same story, at least in one instance? A. Generally the assimilation was consistently higher with honey.

X-Q. 55. At least as compared with this fifth test? A. You see, you would have to take the average of them. You see this (indicating) was much lower than the average of these (indicating).

X-Q. 56. Well, at least as between the first test with Karo corn syrup and the fourth test with honey, there was more absorption of the calcium in the first test than in the fifth test? Is that right? A. It carried back to there.

I may say that I should like Dr. Knott to amplify this,
because she is the one who did the experimental work
42 and she can explain some of these apparent—

X-Q. 57. (interposing) I assume she will.

Now, Dr. Schlutz, you would not attempt to define what a normal infant is, would you? A. That is a little bit difficult; but I think I know, after about forty years of practice, what is regarded as a normal infant.

X-Q. 58. Do you think there is such a thing as a normal infant? A. If you should discuss that with biologists, the definition of a normal infant is quite controversial. But in the opinion of the practicing physician, who has to make the decisions for the parents, I think we do know how to arrive at some estimate or appraisal of what we think is a normal infant and what is not. We are called upon to do it every day and I have been in gold spoon contests when I have almost been hung and murdered for making the decision as to which one is to get the gold spoon and which one is not. But there are ways that we have to determine that clinically.

X-Q. 59. In the case of the tests which were referred to in your affidavits and charts, those studies were balance studies, I assume? A. All of them, yes.

Mr. Moore: That is all.

43 Redirect Examination

By Mr. Noyes:

RD. Q. 60. As you stated before, Doctor, I believe averages have to be considered and not the individual tests. A. Always, yes.

RD. Q. 61. Then, in your statement that your tests consistently show a better result, you were referring to the averages, were you not? A. Yes, to the averages.

RD. Q. 62. In that chart—I will show you a copy of it—down in the lower right hand corner there are two columns marked averages? A. Yes.

RD. Q. 63. And those two columns show that when honey was in the diet there was a better calcium retention than when some other sugar was used? A. Very appreciably better, yes.

Mr. Noyes: No further questions.

By the Court:

RD. Q. 64. Would there be any difference if you fed an infant or a grown person honey one day and gave him some vitamin D the next day? A. Well, you would have separate effects, your Honor. I mean you would have—of course,

honey in itself has no effect like vitamin D in mobil-
44 izing calcium; and it would be difficult to tell from
one day to another; it would be a question of—

RD. Q. 65. (interposing) Suppose you fed them together, in the same meal, that you fed the honey and gave the person vitamin D, wouldn't that have substantially the same effect on the human system? A. I am inclined to think not.

RD. Q. 66. Why not? A. Because it seems that this association of the two together produces a physiological response in the intestinal tract that is different from that which is obtained when the person eats honey and takes a vitamin D preparation.

RD. Q. 67. Where did you get your vitamin D in your preparation? Did you get it alone? A. In our constituents we mainly added it in the form of the crystalline concentrate.

RD. Q. 68. To what? A. The honey.

RD. Q. 69. Honey is absorbed in the stomach, is it not? A. No, in the small bowels.

RD. Q. 70. It is not like the starches? A. Well, of course the starches, practically all the digestion takes place in the small bowel. Very little takes place in the stomach.

RD. Q. 71. Alcohol is digested in the stomach, is
45 it not? A. Not much. There is a little bit absorbed.

RD. Q. 72. Are you sure about that? Isn't honey digested in the stomach? A. No. It passes on to the small bowel and it is there taken up.

RD. Q. 73. The small bowel is right next to the stomach? A. Yes; but it is structurally a very different part.

RD. Q. 74. Now, there is no calcium in honey? A. No.

RD. Q. 75. And there is no calcium in vitamin D? A. No.

RD. Q. 76. So the calcium is put into the body by some kind of food? We consume food that contains it? A. That is right.

RD. Q. 77. Do you have to take that food at the same time that you take the honey and the vitamin D? A. Yes; it is desirable that you have them together.

RD. Q. 78. Then your mixture is composed of more than two things? It is composed of some kind of food having calcium and vitamin D and honey? Is that right? A. Yes.

RD. Q. 79. Do the specifications say that?

Mr. Noyes: Your Honor, we are claiming—

The Court (interposing) I am asking him.

Mr. Noyes: I beg your pardon.

46 By the Court:

RD. Q. 80. Do your specifications say that your honey and vitamin D must be given with some food containing calcium?

Mr. Noyes: I do not believe the doctor has read the patent specification that we have here.

The Witness: I have not seen the specification.

By the Court:

RD. Q. 81. That is the way you do.

Well now, as a matter of fact, isn't the theory of this alleged invention that calcium is already in the system, absorbed from some food, but that it has not been assimilated into the bone or the tissue or entered into the blood stream to the extent that is desirable; and the theory of this application is that it takes that calcium, already in the system, and absorbs it into the system and puts it in the place in the system where it is particularly needed? A. I did not know that that was the contention of the application.

RD. Q. 82. What is it? A. We are looking upon that as a nutritional substance which must be given with some substance containing calcium.

RD. Q. 83. It is not sufficient just to take some food stuff that has calcium in it and thereby to get it into the system?
Is that right? Sometimes it would be absorbed and
47 sometimes it would not? A. You have calcium in
the system to begin with.

RD. Q. 84. You get it from your mother to begin with? A. You have it in your bones and all over.

RD. Q. 85. You get it from your food? A. Yes, sir.

RD. Q. 86. To start out, with the infant, when it takes the mother's milk, that has calcium in it, hasn't it? A. Yes.

RD. Q. 87. Then that calcium has to be absorbed, principally in the bones of the child and, as you say, some of it in the muscles and some of it in the tissues, the nerves and so on? A. Yes.

RD. Q. 88. Well now, in order to get that calcium assimilated or absorbed into the system, where it is needed, you say that you have got to give something that has a solvent, or that will assist the system to absorb it? A. You have to give them a food that contains it.

RD. Q. 89. Granted that you give them a food that contains calcium. Do you say that you have to give something that is a solvent, to get that calcium out of the food and get it into the system, so that it will absorb it? A. Well, you can take calcium from the food without these things present.

RD. Q. 90. Without what things present? A. For instance, vitamin D. You take calcium from the food.
48 This kind of aid was not given earlier. That is why in the earlier days, before we had all these means, we had rickets. Rickets is a condition of the body where the bones do not have adequate calcium, or the system does not mobilize it and assimilate it from the food, so that you have an inadequate intake of calcium.

RD. Q. 91. Unless the system absorbs it, the infant does not get the benefit of it? A. That is correct. Now, it was found that vitamin D enhanced that effect and made the system more readily absorb the calcium that had been taken in.

RD. Q. 92. Vitamin D is in milk? A. Oh, no.

RD. Q. 93. Isn't vitamin D in milk? A. There is a very little in there, between four and fifteen units, very little.

RD. Q. 94. Then, if the infant is lacking in vitamin D, you give him vitamin D? Isn't that right? A. Yes. We know now that we have better infants if from birth on they get vitamin D. We also know that if the infant is artificially fed, not fed by the mother, it is very necessary to put certain carbohydrates in the food, to make him gain and grow. We know that we can not make him grow if we have certain milks, such as cows' milk; so we put certain sugars into the milk; and one of these that we are advocating is honey.

49 RD. Q. 95. It is generally recognized that the refined sugar on the market today has had some of its elements taken away from it? A. Yes; and sucrose is not nearly as effective as honey.

RD. Q. 96. Now, it is generally recognized and has been for years that honey is probably the most easily digested of the sugars. Isn't that right? A. Yes.

RD. Q. 97. There is nothing new about taking that for infant feeding? A. No.

RD. Q. 98. And for ten or fifteen years there has been nothing new about giving them vitamin D? You just happened to think of these vitamins? There is nothing new about giving them to an infant? A. Vitamin D was not generally used at first; but by degrees it came to be given to them.

RD. Q. 99. Aren't there some doctors now who say that the theory of giving the vitamins alone to infants and to grown people is a mistake, that you ought to give them the foods that have these vitamins in them? A. There is some opinion about that; but it is generally agreed that you get a better, more prompt, more quick effect if you give it in some concentrated form.

50 RD. Q. 100. If a person is ill? A. Even if he is not ill. For example, a rachitic case we very quickly restore by giving the concentrate, the sunlight, the proper food. Now, we would not quickly restore the patient if we gave him only the food, because the food contains so little

vitamin D. For example, vegetables contain a very small amount; fruits a little more.

RD. Q. 101. The system, as a rule, does not require a large amount of vitamin D, does it? Take the average person, with average food and diet, that person does not have to take vitamin D at 8 o'clock in the eveing and vitamin D at 10 o'clock the next morning? A. Some of us do not.

RD. Q. 102. You do not take vitamins separately, do you? A. I happen to do so now on the advice of my physician.

RD. Q. 103. I do not. I think the best, safest way, is to take a well balanced diet. Of course, if a person is not well you have to give him some of these things in addition to the usual well balanced diet.

But the point I want to get at is: if the person takes honey in the morning, or some food with vitamin D in it, or vitamin D in the afternoon, that is going to have the same effect as if he took the honey and the vitamin D together,
at the same time. A. Not quite the same effect,
51 because the honey seems to be a vehicle that enables
the system to absorb it.

RD. Q. 104. Have you had any tests about that? Did you make any tests or experiments, of giving the honey and vitamin D at separate times in the day? A. How is that?

RD. Q. 105. Did you make tests or experiments of giving the honey and the vitamin D at separate times during the day? A. We have had tests of honey that are—

RD. Q. 106. (interposing) Well, all your tests with honey and vitamin D were made giving some food in addition to them. Is that right? A. Milk.

RD. Q. 107. Yes. And the milk has practically all the elements that are necessary to sustain life. A. Milk has calcium: but it has not enough—

RD. Q. 108. (interposing) Milk has all the elements necessary to sustain the life of an infant and necessary to sustain a little calf, or whatever it may be. Is't that right? A. Yes, in the early infancy, yes.

The Court: That is all.

(Thereupon the witness retired from the witness stand.)

Mr. Noyes: I would like to call Dr. Knott, please.

52 Thereupon **Dr. Elizabeth Mae Knott** was called as a witness for the plaintiffs and, being first duly sworn, was examined and testified as follows:

Direct Examination

By Mr. Noyes:

Q. 1. Will you please state your name and present residence? A. Elizabeth Mae Knott, 920 East 59th Street, Chicago, Illinois.

Q. 2. And your present occupation? A. I am research associate at the Department of Pediatrics, University of Chicago.

Q. 3. In that capacity you work under Dr. Schlutz? A. I have charge of the nutrition research.

Q. 4. Please state your education and your experience in this work. A. I got my bachelor's degree in home economics, taking a major both in foods and education.

For the following three years I taught foods classes, for both grades and high schools, in a community in Wisconsin.

During that period I took a summer school course at Columbia University, to take special training in nutrition under Dr. Henry Sherman, who is outstanding in nutrition, and Dr. Grace McLeod of the Columbia staff.

53 Then in 1927 and 1929 I was a nutritionist and would have charge of nutrition work for a county and would teach nutrition classes in the schools, all the way from the kindergartens through the high schools, and nutrition work, classes for groups of adults that wanted special instruction.

I also gave nutrition instruction for teachers that would give them university credit.

I was realizing at this time that nutrition was very definitely the field that I wanted to cover more thoroughly and I went back to the University of Wisconsin for a master's degree in nutrition. At that time my instruction was under Steenbock. I had his course in chemistry and in vitamins, so that I had the benefit of his training.

My major professor that year had just returned from study under Dr. Mendell, at Yale, so that I had the benefit of his research.

For the following years I was assistant for the Iowa Research Welfare Station; and the person in charge of that station was Dr. Amy L. Daniels; and I went there because she was one of the most outstanding child nutrition specialists in the country.

I got my Ph. D. degree in nutrition from that institution, under Dr. Daniels' direction.

Since 1935 I have been with Dr. Schlutz, doing research work in nutrition for the Department of Pediatrics at
54 the University of Chicago.

During this last ten years I have also been taking courses in medicine, which I studied to further my understanding of children.

Q. 5. Referring to the tests that Dr. Schlutz described, you have carried on the details of those tests, have you? A. I have been responsible for the details of organization and to see that the technical phases of the experiments were properly carried out, and the analytical data and all of that was under my immediate supervision.

Q. 6. Will you please describe the tests and generally the detail of them and the observations that you had to make and the calculations that you had to make to arrive at the figures obtained? A. The most important part Dr. Schlutz has already commented on.

You have to have an infant who is in good nutritional status to begin with.

Dr. Daniels has specially made note of that in public communications of calcium studies, that if the individual is not in good health in the beginning, the nutrition work that you do during the next few months will not be valid.

So we selected as good infants as we could find. The Cradle physically examined any infant that they took in

and rejected any that they considered not up to par;
55 and we made our own examinations of any that we accepted, before accepting them for our studies.

After I got these infants from The Cradle,—one of them, the youngest, was nine days, and the oldest that I got was six weeks; and I would keep them from two weeks to four weeks, usually four weeks, before starting my tests, so that I knew these children had a preliminary period of good nutrition, with adequate intakes, so that they would be storing calcium at a normal rate before we began our experiments. I did not want them to be short of calcium, because such a pre-period would reflect on our results and make them not valid.

The actual tests involved quantitative intake and quantitative calculation of excreta for a five day period.

Some of the people who have done outstanding work, particularly the University of Iowa, have used a period as short as three days for such observations; but we have not thought that three days was a sufficiently long period, particularly because it was difficult to measure the feces quantitatively; and, since the major portion of the calcium is excreted from the body in the fecal excretions you have got to have the markings of the calcium from the pre-period and for the test period if your results are to be reliable.

So, for those reasons, we chose a five day period for our quantitative calculations and the nurses on the floor were given very careful instructions about the quantita-
56 tive affects of the feeding. The urine bottles were changed every 24 hours; and they did this changing on the hour, so that we knew that our collection of the urine was quantitatively taken, carefully and correctly. I myself always supervised the arranging of the connections for the infant. We had a device of rubber, glove fitting, and taped, so that we could strap this tightly on the infant. We used only male infants, so as to facilitate the handling of the urine.

The feces were covered with acid alcohol as soon as they were passed and stored in the refrigerator.

The urine was preserved with toluene, and enough concentrated hydrochloric acid was added to convert the urine acid to methyl red; and during its collection it was kept under refrigeration conditions at all times, by having an ice pail to keep it cold.

So that we used all the precautions that we could to insure accuracy in our calculations.

At the end of five days the urine was measured and pooled, and aliquots from them were taken for analysis. The fecal excreta were dried, first in the steam bath, and then in the electrical oven, and then stored in the dry form, and aliquots were taken for analysis.

The method used for the calcium determinations is an accepted method, published in Folin's Manual.

I always had my staff that were doing the actual
57 calcium determinations do a series of analyses on
standard solutions, so that I could trust the accuracy
of their work.

We began our first calculation periods in the fall of 1936, with one infant that fall and two infants the following spring.

The shortest time between the periods that we ever used was three days; and we only used that if just a single substance was to be changed in the formula. If two substances were to be changed, we always had a five day or a seven day period between the calculations, in order for equilbrium to be properly established.

The tests were continued when they were about two months of age and were continued until they were about eight months of age. Usually we had about ten test periods. There was only one infant that had a fewer number; and we had only three tests on that particular infant.

We felt that it was quite necessary to continue these tests for a longer period of time, because each infant has a cycle of growth. That is the way human individuals do grow. During certain periods perhaps length will predominate. During other periods perhaps soft tissue growth will be

predominating. Dr. Scanlon, of the University of Minnesota, has particularly published work on such periods of growth. So we did not think that we could trust a single
metabolism observation of a youngster to prove any-
58 thing particular, because that period might happen
to hit a low cycle in the period of bone growth. So
we studied our infants for the four months period of time, taking these quantitative tests at stated intervals.

Altogether we completed tests, 120 tests on the 14 infants in the five years that we were working with this; and during the past year I summarized all those results and they were published this fall in The Journal of Pediatrics.

Q. 7. Doctor, you have referred to an article published in The Journal of Pediatrics.

I hand you a copy of a reprint of an article from that magazine. Is that the article to which you have referred? A. Yes; this is the article; and it is a summary of all of the calcium work that we have done during the last five years time. It includes any other reports that we have submitted on our calcium retention work.

Mr. Noyes: May I offer this reprint in evidence as Plaintiffs' Exhibit 2?

The Court: Yes.

(The reprint so produced and identified was received in evidence and marked PLAINTIFFS' EXHIBIT 2.)

Q. 8. Doctor, you have stated that the results of these tests to which you have referred are given in this article. A. Yes.

Q. 9. Table I gives a tabulation of those tests. A.
59 Table I gives the complete data for every infant that
we have used in these tests.

The periods are numbered. The age and weight of the infant are given, and the formula, what particular type of milk was used. I can state that in general we used three milks, evaporated lactic acid milk, evaporated milk, and dried half-skim milk. A lesser number of tests were made with various other milks.

Our carbohydrate source was either honey or corn syrup; and we varied between those two.

Our vitamin D level is given; and we used either cod liver oil or a crystalline D preparation or a solution of vitamin D from one of the reliable chemical houses.

And the following columns give the intake of calcium per day, the amount that was excreted in the urine, and the amount that was excreted in the feces; also the the total amount that was retained per day and the amount that was retained for the test period of calcium.

The phosphorus figures are incidental to what I am reporting for this present investigation; and so I will not mention those any more.

Q. 10. And is the total of all of the120 tests that you and Dr. Schlutz have spoken of listed here in this table? A. Yes.

Q. 11. And the 14 children are given there as well?
60 A. Yes.

Of course, this table does not begin to show all of the detailed charts that we had to make in order to prepare it; and a short record like this would not include all of the background material that has gone into it.

Q. 12. These figures here might be said to be just calculated results, that is, the results that are calculated from all the observations that you made? A. Yes.

For example, take one of these periods and for the calcium analyses of the feces we would do at least three separate analyses on that; and those figures would have to be in close agreement. If they were not we would repeat the analyses. We would not trust the results unless we had three analyses that were accurate. The data for such as that would fill a couple of these record books, such as I have brought here (exhibiting books).

Q. 13. Now, in this article there is a Chart 3, on page 11. What does that chart represent? A. This chart was prepared to show—well, it is what we call a summary chart. As we have commented, you can not trust individual metab-

olism periods. They have no significance, because you do
not know in which stage of the infant's growth that par-
ticular five day period may have been. It is only when you
have repeated those tests over a period of time and
61 it is only when you have done them on more than one
infant that they have any significance, because, of
course, even normal infants have inherent differences in
the way they will respond, because of the type of inherited
physical characteristics.

So, to interpret the results of Table I, we have prepared a summary chart, which gives the average results for all of the infants that were studied at each type of intake.

Across the top of the chart are given the levels of units of vitamin D, whether in cod liver oil or concentrate, and underneath each one of those are given the results of all the infants that had that particular level of vitamin D, whether it was crystalline vitamin D or the cod liver oil or vitamin D solutions.

In the second of the three lines extending across below the chart, the milk is listed, whether it is an evaporated milk, a dried half-skim milk, breast milk, or protein milk; and all the infants fed on each type of milk are shown.

It is further sub-divided there as to acid conditions.

It is further sub-divided to show whether honey is used as the carbohydrate or corn syrup.

At the bottom are given the number of cases that have been used.

Q. 14. That is the number of metabolism tests? A. The
number of actual metabolism tests at each one of
62 levels.

The thing that really surprised those who were doing this work was the consistency of the results obtained, considering all the variables even after we had properly selected our infants. Each infant is a human being and has his own law of growth; and the thing that surprised us was the consistency in the results, in that for all of the periods the column representing the honey period shows higher results than the one representing all the corn syrup periods. The height of that line, the height of the column, indicates milligrams of calcium that were retained per kilogram of body weight for the infant.

This was true, that as higher levels of vitamin D were included in the formula there was a tendency for the effect of the honey to be less than for the extremely low levels of vitamin D.

For at least certain types of milk there was a tendency for the honey effect to be less when lactic acid had been included, as that itself has a favorable effect.

But even with other factors being present which influence the calcium retentions we found that the average value levels showed a higher response on the honey periods. That was the startling thing to us, that it could be consistent for all of the groups that we studied.

63 Q. 15. In the feeding of infants and in the preparation of formulae for feeding infants can you make any statement as to the desirability of this product? A. Well, I have had considerable first hand experience with mothers who are feeding infants.

It is well known that an artificial formula must have some added type of carbohydrate, in order to approach the composition of human milk. So some source of carbohydrate must be used by the mothers with any artificial feeding; and in our own personal experience we find that the mothers like the use of honey and that it does mix easily with the milk.

I could perhaps contrast that with other substances that are sometimes used, some that the doctors prescribe, such as the lactic acid milk, because it is easily digested by the infant; but that has an extremely difficult formula for the mother to prepare, because the milk must be cooled before the acid is added, or it will curdle; and it involves more time for the mother and she is apt to run into difficulties. And it has a disadvantage, that organisms may develop in that milk during the cooling time. It is more advisable if the milk can be bottled while it is hot, and thus be more sterile.

And so I can state that this mixture of the honey with vitamin D is, from the practical standpoint of the mother, an easy mixture to be used. When the honey is put in with the milk it is sufficiently fluid to go rapidly into solution.

Q. 16. If vitamin D is fed in its usual oil form to an
64 infant, are there any difficulties involved in that? A. Well, it is perhaps the most difficult problem that a mother has with a young infant, if the ordinary cod liver oil is used. There is the difficulty of getting the quantity of oil into the infant's mouth that is necessary to give the proper calcium balance. And, as a further complication, that oil stains the infant's clothing, so that for a young mother who has to feed her infant—well, they usually give the cod liver oil while the infant is stripped for the bath, so that they won't stain the clothing; and it is a struggle, whether the cod liver oil goes down the infant's throat or is spit out.

If you have a thing that is miscible with the milk—you can't put an oily substance into the bottle, because it won't pass through the nipple. Of course some will go through the nipple. If you have a substance that is completely miscible with the milk, then the infant is assured that he will take it and it is quantitatively consumed.

Q. 17. Would this product, with the honey and vitamin D, be in the aqueous or oily form or the dispersed crystalline form? All three of those would be miscible with the milk? A. The aqueous form and the crystalline form are more miscible; but even if the oily form were in advance mixed with the honey, it would be dispersed because of its intimate relation.

65 Q. 18. And you would not have that coating of the bottle? A. It would not have the same effect, as if you had tried to add in the home a teaspoonful of oil at the time of mixing it, because you would not have the facilities for mixing it with the milk.

Q. 19. Doctor, it was known, was it not, prior to all these tests that honey, as a sugar, is readily digested? A. Yes; we have known that for a long time.

Our first work at Chicago was on the absorption of honey; and we were doing some of that work before it was suggested to us doing some of these calcium studies. Honey is particularly easy digested, because it contains the natural sugars. It is a monosaccharide. Sucrose, the ordinary cane sugar, is termed a disaccharide; and that has to be split by the digestive juices before it can be absorbed into the blood stream.

Q. 20. Prior to these tests was it known that honey and vitamin D had any effect in increasing the calcium absorption over that obtained by the vitamin D with ordinary sugar? A. To the best of my knowledge no one has ever known that there was such an effect.

I have tried to review all of the literature dealing with honey and I have furthermore reviewed all of the literature dealing with calcium studies with infants; and I have found no mention of that.

Mr. Noyes: That is all.

66 Cross-examination

By Mr. Moore:

X-Q. 21. Dr. Knott, in this file of the Straub application there is still another affidavit of Dr. Schlutz, executed the 24th day of July, 1939. That is Dr. Schlutz's signature, isn't it (exhibiting Plaintiffs' Exhibit 1)? A. I believe it to be.

X-Q. 22. Now, he said in that affidavit—I quote:

"That there are variable human idiosyncrasies and conditions in each individual child which affect the amount of calcium which will be retained by that child at any given time regardless of the combination fed. In other words, that the condition of the child at a particular time is a factor affecting the amount of calcium which will be retained regardless of the combination fed."

I judge from the testimony that you have given that you agree with that point. A. Yes. I have been trying to stress that that is the reason we use average results instead of single metabolism periods.

XQ. 23. Now, your study of the effects of honey upon calcium retentions, in infants, is set forth in this Plaintiffs' Exhibit No. 2? A. Yes.

67 XQ. 24. Those tests are concerned, are they not, with the effect of honey upon calcium retentions? A. Yes.

XQ. 25. And your conclusion is that honey is "a type of carbohydrate which is well suited to the infant's needs and therefore probably deserves a wider use in infant dietaries." Is that right? A. Yes; we feel that it is a good source of carbohydrates.

XQ. 26. But your conclusion is directed to the honey, the use of honey? A. I believe it is so stated there.

Mr. Moore: That is all.

The Court: Is that all?

Redirect Examination

By Mr. Noyes:

Re-D. Q. 27. Dr. Knott, in all these tests that you made there was some vitamin D present, was there not? A. Yes; there was the D that was carried by the milk present in all of the cases; and the amount of that varied from—well, I don't know the exact amount, because we did not analyze each day's lot of milk that we would use. But from other tests that have been done by other people, we know that at best it did not furnish over, probably, four units of D per day.

68 We did test our honey itself for D content and found that it had no D.

Mr. Noyes: That is all.

(Thereupon the witness retired from the witness stand.)

APPELLANTS' EXHIBIT NO. 2.

FILED
DEC 30 1942
CHARLES E. STEWART, Clerk

THE EFFECT OF HONEY UPON CALCIUM RETENTIONS IN INFANTS

E. M. KNOTT, PH.D.
C. F. SHUKERS, M.D.
and
F. W. SCHLUTZ, M.D.
Chicago, Ill.

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THE EFFECT OF HONEY UPON CALCIUM RETENTIONS IN INFANTS

E. M. Knott, Ph.D., C. F. Shukers, M.D., and F. W. Schlutz, M.D.
Chicago, Ill.

IN A recent publication[3] we have discussed the use of honey as a carbohydrate in infant feeding. On the basis of the general well-being of the infant, the number of stools per day, weight gains, and blood sugar tolerance studies, we concluded that honey would seem to be well suited to the infant's needs. In the present paper we wish to offer data in regard to the effect of honey upon calcium retentions.

Our report contains data from fourteen healthy male infants studied during the first six months of their lives. A total of 120 metabolism periods have been completed on these normal infants. Honey as a source of carbohydrate was compared with corn syrup for different types of milks and for varying levels of vitamin D. For fifty-nine of the metabolism periods the infants were fed formulas containing evaporated milk either with or without lactic acid. During fifty periods dried half-skim milk was used, while for seven and four periods, respectively, the infants received breast milk and dried protein milk. Vitamin D was usually furnished in the form of cod-liver oil at varying levels, but during certain periods either solutions of a crystalline preparation or Drisdol was used. Additional vitamins and minerals were furnished by supplements of cevitamic acid, thiamin, carotene, ferric pyrophosphate, and copper sulfate.

During the metabolism periods, which were always of five days' duration each, the feedings were given to the infants without loss, and the bottles were rinsed with distilled water which was either consumed at once or added to the next feeding. A rest period of three days was allowed for adjustment between collection periods, unless an important change in formula had been made, in which case five to seven days were given to permit a return to equilibrium.

Urine and feces were quantitatively collected during the five-day metabolism periods. The urine was preserved by toluene and refrigeration, enough concentrated hydrochloric acid being added to make the urine acid to methyl red. Feces were marked off by carmine and preserved during the collection period by acid alcohol (5 per cent glacial acetic acid in 95 per cent alcohol) and refrigeration. The feces were prepared for analysis by drying to constant weight, at first on a steam

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Assistance in the preparation of these materials was furnished by the personnel of Work Projects Administration Official Project No. 665-54-3-387.

The various milks were furnished through the courtesy of the Evaporated Milk Association, the Borden Company, and Mead Johnson & Company. Honey, carefully selected as to source, purity, and uniformity, was supplied by the Lake Shore Honey Company.

Table I

Average Daily Calcium Balances

SUBJECT	PERIOD	AGE (WK.)	WT. (KG.)	FORMULA*	VITAMIN D (I.U.)	CALCIUM					PHOSPHORUS	
						INTAKE (GM./DAY)	URINE (GM./DAY)	FECES (GM./DAY)	RETENTION (GM./DAY)	RETENTION (MG./KG.)	INTAKE (GM./DAY)	FECES (GM./DAY)
John	1	9	4.78	E. LA.-CS.	170	0.647	0.007	0.513	0.127	26.5	0.521	
	2	11	4.99	E. LA.-CS.	170	0.656	0.004	0.549	0.103	20.6	0.521	
	3	12	5.27	E. LA.-H.	170	0.731	0.008	0.532	0.192	36.5	0.575	
	4	13	5.42	E. LA.-H.	170	0.691	0.003	0.494	0.195	36.0	0.575	
	5	14	5.76	Evap.-H.	170	0.772	0.003	0.635	0.134	23.3	0.644	
	6	16	6.05	Evap.-H.	170	0.720	0.006	0.494	0.221	36.4	0.644	
	7	17	6.43	Evap.-H.	170	0.754	0.005	0.522	0.227	35.3	0.644	
	8	19	6.76	Evap.-H.	170	0.783	0.006	0.542	0.235	34.7	0.644	
	9	20	6.99	Evap.-H.	170	0.669	0.006	0.516	0.148	21.1	0.644	
	10	22	7.15	Evap.-H.	680	0.745	0.009	0.511	0.225	31.5	0.644	
Bart	1	6	4.13	Dry.-H.	1,000	0.824	0.001	0.539	0.284	68.7	0.610	
	2	7	4.43	Dry.-H.	1,000	0.942	0.004	0.626	0.312	70.5	0.696	
	3	12	5.27	Dry.-H.	170	1.177	0.005	0.830	0.342	65.2	0.870	
	4	14	5.48	Dry.-H.	170	1.177	0.005	0.808	0.365	66.6	0.870	
	5	15	5.82	Dry.-CS.	170	1.295	0.004	1.038	0.253	44.2	0.958	
	6	16	6.16	Dry.-CS.	170	1.412	0.006	1.030	0.377	62.9	1.044	
	7	18	6.35	Dry.-H.	170	1.412	0.012	1.176	0.224	35.7	1.044	
	8	19	6.39	Dry.-H.	170	1.412	0.012	1.025	0.375	58.5	1.044	
Hal	1	8	3.64	E. LA.-H.	0	0.602	0.008	0.420	0.174	45.3	0.470	
	2	9	3.90	E. LA.-H.	0	0.587	0.003	0.427	0.157	39.0	0.457	
	3	11	4.25	E. LA.-H.	0	0.642	0.004	0.478	0.161	37.8	0.500	
	4	12	4.52	E. LA.-H.	1,000	0.636	0.006	0.423	0.207	45.8	0.500	
	5	13	4.78	E. LA.-H.	1,000	0.640	0.004	0.411	0.225	47.2	0.500	
	6	15	5.04	E. LA.-H.	1,000	0.640	0.011	0.435	0.194	38.5	0.500	
	7	20	5.55	Dry.-H.	680	1.129	0.008	0.681	0.439	79.1	0.870	
	8	21	5.80	Dry.-H.	680	1.129	0.009	0.752	0.367	63.4	0.870	
	9	23	6.35	Dry.-H.	680	1.298	0.014	0.799	0.485	76.4	1.000	
	10	25	6.63	Dry.-H.	680	1.298	0.025	1.039	0.234	35.2	1.000	
	11	26	6.94	Dry.-H.	680	1.399	0.014	0.727	0.659	94.9	1.080	

Ned	2	9	3.99	Dry.-H.	170	1.099	0.025	0.978	0.097	24.4	0.782	0.229
	3	13	4.45	Dry.-H.	170	1.222	0.033	1.116	0.073	16.4	0.870	0.242
	4	16	4.82	Dry.-CS.	170	1.222	0.031	1.091	0.099	20.6	0.870	0.273
	5	17	5.10	Dry.-CS.	170	1.344	0.039	1.261	0.045	8.7	0.958	0.336
	6	19	5.44	Dry.-CS.	170	1.344	0.059	1.265	0.020	3.6	0.958	0.352
	7	20	4.68	Dry.-CS.	170	1.466	0.042	1.354	0.071	12.5	1.044	0.348
	8	21	5.88	Dry.-H.	170	1.466	0.055	1.175	0.236	40.2	1.044	0.315
	9	23	6.10	Dry.-H.	170	1.588	0.060	1.424	0.104	17.1	1.132	0.395
	10	24	6.36	Dry.-H.	170	1.588	0.039	1.540	0.010	1.5	1.132	0.524
Myles	3	11	4.41	Dry.-H.	170	1.099	0.025	1.010	0.064	14.6	0.782	0.383
	4	12	4.64	Dry.-H.	170	1.099	0.027	0.936	0.136	29.3	0.782	0.386
	5	14	4.80	Dry.-CS.	170	1.099	0.026	0.950	0.123	25.6	0.782	0.315
	6	15	5.01	Dry.-CS.	170	1.222	0.030	1.005	0.187	37.2	0.870	0.315
	7	18	5.47	Dry.-CS.	170	1.222	0.029	1.048	0.144	26.3	0.870	0.358
	8	19	5.78	Dry.-CS.	170	1.344	0.050	1.199	0.095	16.4	0.958	0.399
	9	21	5.94	Dry.-H.	170	1.344	0.053	1.202	0.089	14.9	0.958	0.482
	10	22	6.19	Dry.-H.	170	1.466	0.045	1.093	0.328	52.9	1.044	0.327
	11	23	6.43	Dry.-H.	170	1.466	0.038	1.317	0.110	17.1	1.044	0.522
Jack	1	7	4.21	Dry.-H.	100	1.096	0.047	0.999	0.050	11.9	0.820	0.276
	2	8	4.52	Dry.-H.	100	1.096	0.041	0.719	0.336	74.3	0.820	0.217
	3	10	4.78	Dry.-H.	100	1.212	0.047	0.947	0.218	45.7	0.908	0.295
	4	11	5.03	Dry.-H.	100	1.327	0.054	1.021	0.252	50.1	0.994	0.337
	5	12	5.46	Dry.-H.	200	1.442	0.037	1.351	0.054	9.9	1.080	0.463
	6	14	5.64	Dry.-H.	200	1.442	0.040	1.164	0.238	42.1	1.080	0.348
	7	17	5.97	Pro.-H.	200	2.110	0.100	1.880	0.130	21.7	1.141	0.419
	8	18	6.36	Pro.-H.	200	2.110	0.121	1.626	0.363	57.1	1.141	0.413
Noel	1	15	6.30	Dry.-H.	0	1.500	0.039	1.474	-0.013	-2.0	1.124	0.509
	2	16	6.67	Dry.-H.	0	1.500	0.033	1.331	0.136	20.4	1.124	0.555
	3	18	7.10	Dry.-H.	0	1.615	0.031	1.402	0.182	25.7	1.210	0.600
	4	19	7.32	Dry.-H.	0	1.615	0.041	1.403	0.172	23.5	1.210	0.621
	5	20	7.63	Dry.-H.	200	1.584	0.026	1.484	0.074	9.7	1.188	0.649
	6	22	7.55	Dry.-H.	200	1.486	0.012	1.339	0.135	17.9	1.132	0.517
	7	25	7.63	Pro.-H.	200	2.110	0.106	1.780	0.224	29.3	1.141	0.515
	8	26	7.84	Pro.-H.	200	2.179	0.093	1.889	0.197	25.1	1.179	0.576

*E. LA., evaporated lactic acid milk; Evap., evaporated milk; Dry., dried half-skim milk; Pro., dried protein milk; Br., breast milk; H., honey; CS., corn syrup.

TABLE I—CONT'D

SUBJECT	PERIOD	AGE (WK.)	WT. (KG.)	FORMULA*	VITAMIN D (I.U.)	CALCIUM					PHOSPHORUS	
						INTAKE (GM./DAY)	URINE (GM./DAY)	FECES (GM./DAY)	RETENTION (GM./DAY)	RETENTION (MG./KG.)	INTAKE (GM./DAY)	FECES (GM./DAY)
Guy	1	7	3.83	Evap.-H.	170	0.540	0.022	0.401	0.117	30.5	0.365	
	2	9	4.10	Evap.-H.	170	0.540	0.012	0.361	0.167	40.7	0.365	0.088
	3	10	4.44	E. LA.-CS.	170	0.617	0.017	0.433	0.167	37.6	0.418	0.062
	4	12	4.76	E. LA.-H.	170	0.655	0.016	0.391	0.248	52.1	0.443	0.055
	5	14	5.08	E. LA.-H.	340	0.720	0.022	0.402	0.296	58.3	0.487	0.051
	6	15	5.32	E. LA.-CS.	340	0.745	0.024	0.449	0.272	51.1	0.504	0.071
	7	17	5.66	E. LA.-H.	500	0.771	0.033	0.427	0.314	55.5	0.521	0.047
	8	19	5.97	E. LA.-CS.	500	0.848	0.020	0.557	0.271	45.4	0.521	0.106
	9	20	6.33	E. LA.-CS.	500	0.874	0.029	0.570	0.275	43.4	0.590	0.167
	10	22	6.74	E. LA.-CS.	170	0.874	0.033	0.447	0.394	58.5	0.590	0.099
	11	24	6.99	E. LA.-CS.	170	0.874	0.037	0.461	0.376	53.8	0.590	0.107
Geoffery	1	8	4.22	Evap.-H.	170	0.617	0.042	0.386	0.188	44.6	0.418	0.101
	2	10	4.26	Evap.-H.	170	0.617	0.043	0.371	0.203	47.7	0.418	0.106
	3	11	4.54	E. LA.-CS.	170	0.694	0.042	0.442	0.210	46.3	0.470	0.064
	4	13	4.87	E. LA.-H.	170	0.694	0.054	0.387	0.253	52.0	0.470	0.057
	5	15	5.15	E. LA.-H.	340	0.745	0.056	0.408	0.281	54.5	0.504	0.055
	6	16	5.36	E. LA.-CS.	340	0.745	0.064	0.406	0.276	51.4	0.504	0.056
	7	18	5.56	E. LA.-H	500	0.797	0.051	0.437	0.309	55.6	0.539	0.054
	8	20	5.83	E. LA.-CS.	500	0.900	0.056	0.621	0.223	38.2	0.609	0.132
	9	21	6.12	E. LA.-CS.	500	0.925	0.048	0.683	0.194	31.6	0.626	0.215
	10	23	6.44	E. LA.-CS.	170	0.951	0.060	0.662	0.229	35.6	0.644	0.121
	11	25	6.79	E. LA.-CS.	680	0.951	0.064	0.704	0.183	26.9	0.644	0.154
Nicky	1	12	3.74	E LA.-H.	0	0.542	0.035	0.406	0.102	27.2		
	2	13	3.92	E. LA.-CS.	0	0.567	0.029	0.520	0.016	4.2		
	3	15	4.13	E. LA.-H.	170	0.587	0.034	0.455	0.098	23.7		
	4	17	4.30	E. LA.-CS.	170	0.633	0.043	0.460	0.129	30.0		
	5	18	4.49	Evap.-CS.	170	0.633	0.030	0.520	0.082	18.4		
	6	20	4.69	Evap.-H.	170	0.716	0.029	0.446	0.242	51.5		
	7	23	5.34	Dryco and lactic acid.-H.	170	1.102	0.054	0.912	0.136	25.4		
	8	24	5.59	Dry.-CS.	170	1.259	0.059	1.047	0.153	27.4		
	9	28	6.17	Dry.-CS.	170	1.417	0.045	1.348	0.024	3.9		

Gus	1	9	4.00	E. LA.-H.	0	0.610	0.019	0.478	0.114	28.5		
	2	11	4.25	E. LA.-CS.	0	0.610	0.021	0.476	0.114	26.8		
	3	12	4.53	E. LA.-H.	170	0.633	0.038	0.372	0.223	49.3		
	4	14	4.74	E. LA.-CS.	170	0.678	0.039	0.431	0.208	43.8		
	6	17	5.21	Evap.-H.	170	0.788	0.023	0.537	0.227	43.6		
	7	20	5.58	Dryco and lactic acid.-H.	170	1.154	0.064	0.627	0.464	83.1		
	8	22	6.21	Dry.-CS.	170	1.312	0.074	1.022	0.217	34.9		
	9	25	6.55	Dry.-CS.	170	1.417	0.040	1.332	0.045	6.8		
Kenneth	1	8	4.15	Br.	170	0.174	0.010	0.145	0.018	4.4		
	2	9	4.37	Br.	170	0.173	0.012	0.114	0.048	10.9		
	4	13	5.26	Evap.-CS.	170	0.725	0.007	0.493	0.225	42.8		
	5	14	5.51	Evap.-H.	170	0.773	0.006	0.522	0.245	44.5		
	6	15	5.85	Evap.-H.	170	0.773	0.067	0.538	0.228	38.9		
	7	17	6.14	E. LA.-H.	170	0.797	0.019	0.494	0.285	46.3		
	8	19	6.43	E. LA.-CS.	170	0.797	0.025	0.487	0.286	44.4		
	9	20	6.81	Dry.-CS.	170	1.153	0.027	0.905	0.222	32.6		
Buddy	1	8	3.50	Br.	170	0.152	0.005	0.127	0.019	5.6		
	2	9	3.61	Br.	170	0.152	0.010	0.093	0.049	13.6		
	4	13	4.04	Evap.-CS.	170	0.580	0.006	0.510	0.064	15.7		
	5	14	4.30	Evap.-H.	170	0.677	0.006	0.551	0.119	17.7		
	8	19	4.95	E. LA.-CS.	170	0.761	0.010	0.513	0.238	48.0		
	9	20	5.01	Evap.-CS.	170	0.761	0.006	0.570	0.186	37.0		
	10	21	5.23	Evap.-H.	170	0.797	0.008	0.671	0.118	22.5		
Billy	1	8	4.73	Br.		0.207	0.006	0.141	0.060	12.7		
	2	10	5.15	Br.		0.207	0.009	0.100	0.098	19.1		
	3	11	5.43	Br.		0.207	0.008	0.106	0.093	17.1		

*E. LA., evaporated lactic acid milk; Evap., evaporated milk; Dry., dried half-skim milk; Pro., dried protein milk; Br., breast milk; H., honey; CS., corn syrup.

bath, and then in an electric oven maintained at 65° C. Aliquots of the urine for calcium analyses were evaporated and wet-ashed, while fecal aliquots were weighed on the analytical balance and ashed in a muffle furnace. Calcium determinations were done according to the method of Fiske and Logan.[1] Magnesium analyses for eighty-two periods were made on the filtrates from the calcium determinations and are reported elsewhere.[4] Phosphorus determinations were also done on some of the materials by the method of Fiske and Subbarrow.[2]

The detailed results for the 120 metabolism periods are reported in Table I. In addition to calcium intakes, excretion, and retention, the table includes data regarding the age, weight, and diet of the infant for each period. In order to evaluate the effect of honey, the data have been analyzed in various ways to facilitate our interpretation of results.

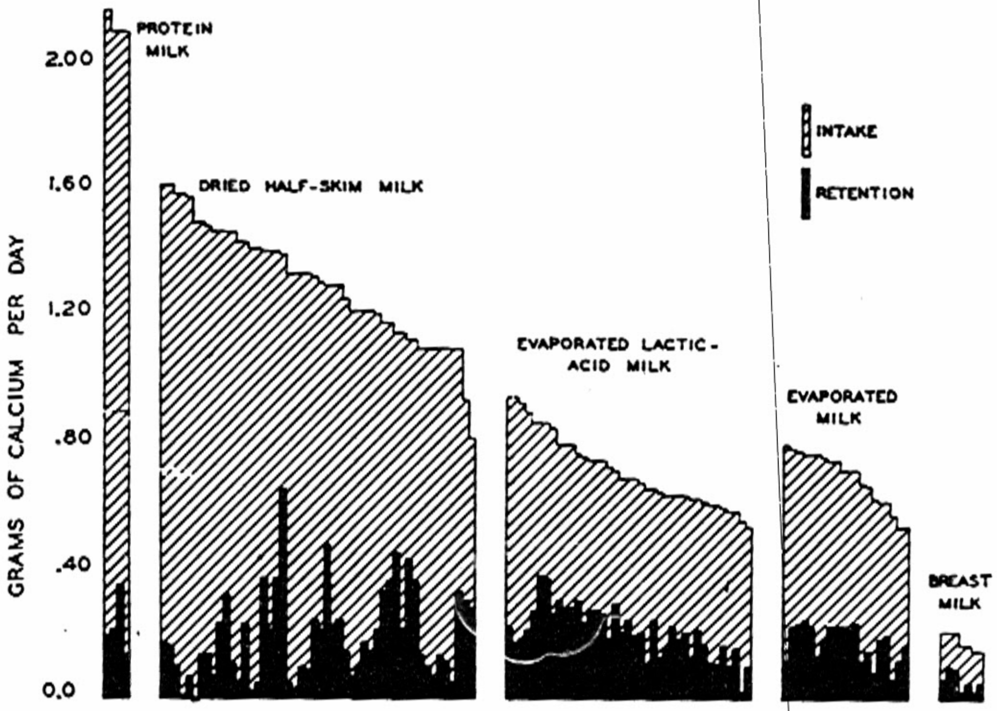

Chart 1.—Individual retentions of calcium in relation to calcium intakes. Each column represents results for one infant during one five-day metabolism period.

In Chart 1 the total daily retentions for the individual infants are arranged in relation to the calcium intakes for the different metabolic periods. The average milligrams of calcium retained per kilogram of body weight, for successively decreasing amounts of intake, were as follows: 24.6, 9.3, 35.0, 31.6, 28.9, 45.8, 40.6, 49.3, 43.4, 36.9, and 25.9. It is at once apparent that although there was a trend downward in retentions for lower levels of calcium intakes, higher levels of calcium gave unpredictable retentions which were not uniformly related in magnitude to the intakes. The greatest variability in results occurred when dried half-skim milk formulas were used and total retentions ranged from -0.013 to 0.659 Gm. per day. We can therefore conclude that low calcium intakes may limit calcium retentions, but high intakes do not insure high retentions.

In addition to the level of calcium intake, a second factor affecting calcium retentions was the amount and source of vitamin D. In Table II the average results have been calculated for each level of vitamin D

TABLE II

RETENTIONS OF CALCIUM IN RELATION TO VITAMIN D INTAKE

VITAMIN D (I. U.)	MILK	NO. OF PERIODS	CALCIUM RETENTIONS GM./DAY
1,000	Dried half-skim milk	2	0.298
1,000	Evaporated lactic acid milk	3	0.209
680	Dried half-skim milk	5	0.437
680	Evaporated milk	1	0.225
680	Evaporated lactic acid milk	1	0.183
500	Evaporated lactic acid milk	6	0.264
340	Evaporated lactic acid milk	4	0.281
200	Dried half-skim milk	4	0.125
170	Dried half-skim milk	31	0.169
170	Evaporated milk	19	0.178
170	Evaporated lactic acid milk	18	0.220
100	Dried half-skim milk	4	0.214
0	Dried half-skim milk	4	0.120
0	Evaporated lactic acid milk	7	0.120

administered with each type of milk. With some of the levels the number of cases is too small to permit valid conclusions, but certain trends in results have been observed. As was to be expected, the lowest retentions of calcium occurred when no supplementary vitamin D was given. The average low value of 0.120 Gm. of calcium per day was retained during eleven periods, when irradiated milk was the only source of vitamin D. This low average value of 0.120 Gm. was the same for both half-skim dried milk (four periods) and for evaporated milk (seven periods).

Cod-liver oil was the source of vitamin D for the three levels of 170, 340, and 680 units. When the vitamin D was increased from 170 to 680 units with the dried half-skim milk formulas, there was an increase in the average calcium retentions from 0.169 to 0.437 Gm. per day. An increase in vitamin D from 170 to 340 units with evaporated lactic acid milk formulas correlated with a smaller increase in retentions from 0.220 to 0.281 Gm. It will be noted that at 170 units, the 0.220 Gm. of calcium retained on evaporated lactic acid milk was considerably higher than the 0.169 Gm. figure obtained with dried half-skim milk. With plain evaporated milk plus 170 units of vitamin D, the retention average of 0.178 Gm. was between the results obtained with the other two types of milk on this amount of vitamin. With both plain evaporated milk and lactic acid evaporated milk, two cases at 680 units had relatively low retentions. These results are undoubtedly influenced by the level of calcium ingestion on these different types of milk, and by the inherent differences in individual infants. We can conclude that at low levels of vitamin D, higher retentions of calcium were observed with the

evaporated milks, especially evaporated lactic acid milk, than occurred with the dried half-skim milk; but at high levels of vitamin D intake, highest retentions were obtained with the dried milk.

A solution of a crystalline vitamin D preparation was used for the levels of 100, 200, and 1,000 units per day. Results here did not correlate with vitamin D intake as might have been anticipated, and the average retentions of calcium were lower than those for comparable levels of cod-liver oil. It may be that this preparation was not as potent in vitamin D content as would have been expected from its accompanying label, although discrepancies in results may partially have been due to inherent differences in individual infant types.

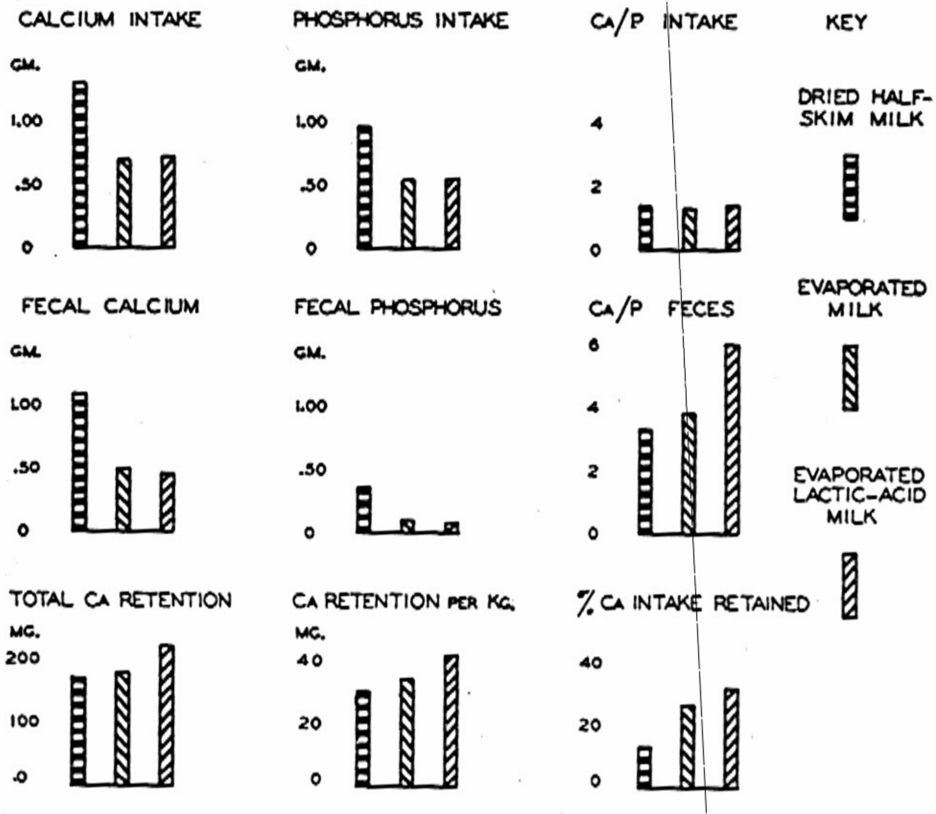

Chart 2.—Average results for all periods with 170 units of vitamin D.

To facilitate further evaluation of the data, Chart 2 has been prepared for the average results obtained with 170 units of vitamin D for each of the three types of milk studied. At this level of vitamin intake, significant numbers of cases were studied, and thirty-one metabolism periods were included in the averages for dried half-skim milk, while nineteen and eighteen periods, respectively, were studied for plain evaporated milk and evaporated milk plus lactic acid. The total calcium retentions for these milks were, as previously stated, 0.169, 0.178, and 0.220 Gm. per day. The retentions calculated per kilogram of body weight show the same trend, being 29.9 mg. for dried half-skim milk, 34.1 mg. for evaporated milk, and 41.2 mg. for the evaporated milk plus lactic acid. The lactic acid undoubtedly promoted favorable

conditions in the intestinal tract for calcium and phosphorus absorption. It is interesting to note how the processes of digestion and absorption have affected the Ca/P relationships. The ratios of the intakes of calcium and phosphorus average between 1.3 and 1.4 for all three milks. With dried half-skim milk periods, the Ca/P ratio in the feces has been moderately altered to 3.25. Plain evaporated milk periods give an average fecal Ca/P ratio of 3.85, indicating relatively greater absorption of phosphorus from the intestinal tract. With lactic acid evaporated milk periods, however, the ratio of Ca/P in the feces has shifted to 6.10, showing very efficient use of the ingested phosphorus. The increased efficiency in utilization of phosphorus correlates with the greater percentage of calcium intake which is retained during the lactic acid evaporated milk periods.

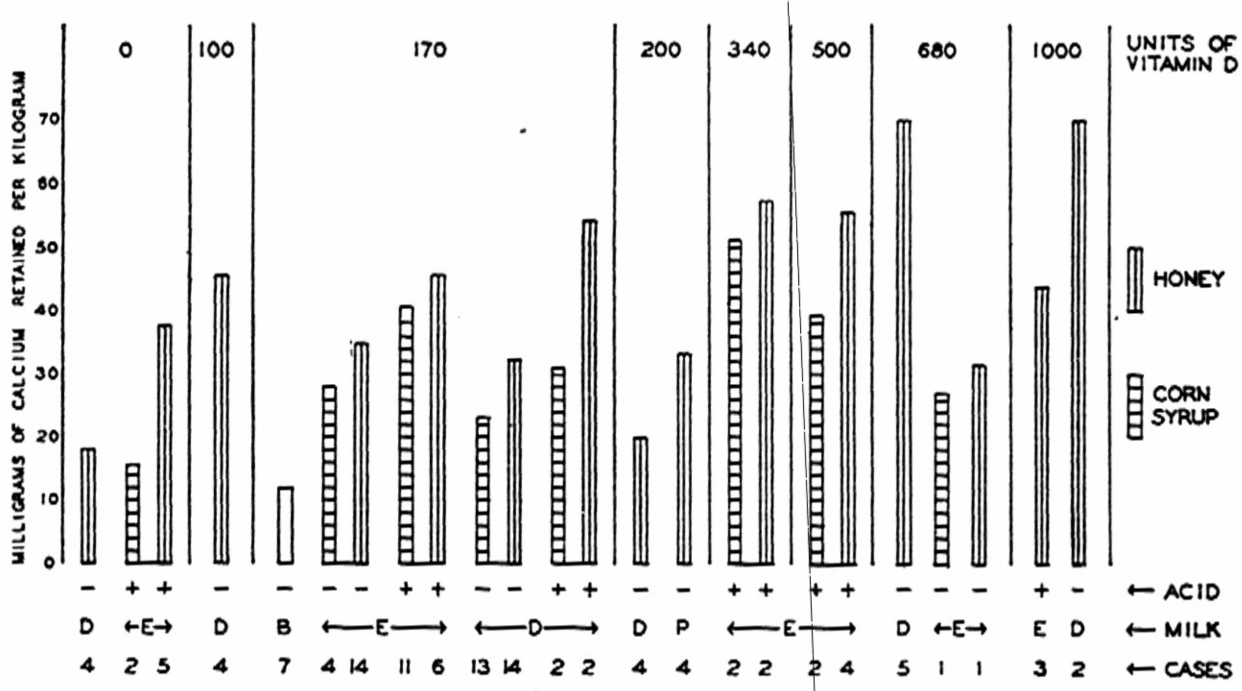

Chart 3.—Retention of calcium in relation to type of carbohydrate, amount of vitamin D, and use of lactic acid. *D*, dried half-skim milk; *E*, evaporated milk; *B*, breast milk; *P*, protein.

In the discussion thus far, we have commented upon how the level of calcium intake, the amount of vitamin D administered, the type of milk fed, and the use of lactic acid have affected the retentions of calcium. Although these factors are important, they are not the only ones which influenced the amount of calcium retained by the infants in this study. A significant factor was the type of carbohydrate used. In Chart 3 the data have been divided to show the effects of honey in contrast to results with corn syrup. Wherever bars join the honey and corn syrup columns, the same infants were fed under comparable conditions to make the comparison of these two types of carbohydrate completely valid. It will be noted that for all the paired periods studied, the average retention of calcium was always higher if honey had been included in the formula. These increased retentions when honey was

fed occurred both with low and with high intakes of vitamin D and occurred regardless of the type of milk fed or the use of lactic acid. Honey would seem, therefore, to have a definite beneficial influence upon the retention of calcium by young infants.

91

The uniform improved response with honey is of special interest in view of the variability in results observed for some of the other factors which affected calcium balances. Although a few individual infants had higher results on corn syrup when paired periods were compared, the majority of the infants had better results on honey, and the averages for all the paired periods were consistently in favor of honey.

In analyzing the data further, it is apparent that while the favorable influence of honey occurred regardless of what other factors were operating to affect the calcium retentions, the magnitude of improved response on honey tended to decrease as other beneficial factors were also employed. This is to be expected, since each infant has an upper level of response which is optimal for his storage of calcium. When a type of milk was fed which permitted adequate absorption of calcium and phosphorus, when higher levels of reliable vitamin D sources were given, or when lactic acid had been added to the milk, honey produced a lesser degree of response, but even with these factors operating to produce satisfactory retentions, the use of honey could still improve results.

In view of the results presented in this and previous papers, we conclude that honey is, indeed, a type of carbohydrate which is well suited to the infant's needs and therefore probably deserves a wider use in infant dietaries.

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APPELLEES' EXHIBIT NO. 1.

183 Endorsed: Filed Dec 30 1942 Charles E. Stewart, Clerk

WALTER F. STRAUB and W. F. STRAUB & COMPANY,

Civil Action No. 8069.

A—Steenbock,	1,680,818
B—Rasky,	1,892,902
C—Crane,	1,911,882
D—Bresnick,	2,007,108
E—Hall,	2,022,464
F—Hooper,	2,030,792

Patented Aug. 14, 1928. **1,680,818**

UNITED STATES PATENT OFFICE.

HARRY STEENBOCK, OF MADISON, WISCONSIN, ASSIGNOR TO WISCONSIN ALUMNI RESEARCH FOUNDATION, A CORPORATION.

ANTIRACHITIC PRODUCT AND PROCESS.

No Drawing. Application filed June 30, 1924. Serial No. 723,171.

This invention relates particularly to a method of preparing antirachitic products of edible character, such as foods and medicines, and to the products obtained by such method of treatment.

The process is effected by subjecting edible substances to the action of rays of the region of the ultra violet rays of the spectrum in such manner as to effect the antirachitic activation, care being taken to avoid the destruction of the antirachitic principle after it has been imparted. The sterilization of water by means of ultra violet rays is known. Also, it has been proposed to sterilize milk by means of ultra violet rays, but the treatment given to the milk to effect sterilization has also had the effect of spoiling the taste and otherwise injuring the milk, and thus this method of sterilization has failed to come into commercial use. Also, it has been proposed to employ X-rays, or Roentgen rays, to effect sterilization. These rays are not suited to the present purpose, however.

It has not been known prior to the present invention that it is possible to so treat edible products by the use of ultra violet rays as to render them antirachitic. The present invention enables this to be effected with a wide variety of edible substances suited to the needs of mankind and animals. The treatment is understood to impart other favorable properties to the substances treated.

It is known that the so-called vitamins possess various properties and are intimately concerned with the maintenance of bodily processes, and thus are inseparably connected with the normal physiology of the animal, including man. Thus, it is commonly accepted that vitamin A functions to prevent certain types of infections, because its absence from the diet results in inflammation of the eyes, or inflammation of the respiratory tract, the growth of the animal ceases, and, if the condition be not corrected, death usually results from pneumonia; the absence of vitamin B from the diet is likely to result in cessation of growth, paralysis of the digestive tract, failure of appetite, ultimate neuritis, and death from convulsions; and the absence of vitamin C from the diet is likely to result in scurvy, hemorrhages, and accompanying distressing symptoms. Also, there is now supposed to exist a vitamin known as the antirachitic vitamin, whose function is to preserve the normal deposition of calcium salts in the bones, thus preventing rachitis, or the disease commonly known as rickets. Again, there is supposed to exist a substance known as factor X, which is concerned with the maintenance of the function of reproduction.

The present invention is particularly concerned with the so-called antirachitic vitamin, but it is to be observed that it is possible to prepare food stuffs for man, and feeds for animals, possessing the properties, or principle, of two or more of the so-called vitamins. The same is true with respect to medicines.

It has long been known that cod liver oil is an excellent therapeutic agent for the prevention and cure of rickets in children. This product, known on the market as cod liver oil, is produced from the livers of certain fishes, most notably the cod fish. However, cod liver oil is not well adapted for use in foods, or as medicine, because of its highly objectionable odor and taste.

It was first supposed that fats, generally, might possess the antirachitic principle, but it has been found that such is not the case; and it is now known that the antirachitic vitamin is not generally distributed in nature, and this fact is attested to by the fact that rickets is a disease common to man and animals to a surprising degree. It has been stated in the Etiology of Rickets by E. A. Park, Physiological Reviews, vol. 3, p. 111, 1923: "Schmorl (6) found that ninety per cent of the children in Dresden under four years of age who died between the years 1901 and 1908 and more than ninety-six per cent of the infants showed evidences of rickets, and Hess (23) himself has reported that rickets was exceedingly prevalent among the children in the Hebrew Infant Assylum in New York city, where presumably the chemical investigations of the blood were made." There are many manifestations of rickets, including permanent deformity of the legs, contracted pelves, chests, maxilla and abnormal dentition.

The present invention has for its primary object the provision of a process by which various articles of food and various medicines may have imparted to them the antirachitic principle, or factor, and thus be rendered antirachitically active, in a very simple and effective manner, and without rendering such products objectionable, in any degree, from the standpoint of odor and taste.

Referring again to the subjects of fats, generally, with the exception of cod liver oil, fats are generally lacking in the antirachitic factor. Butter is known to contain the vitamin A, and, in a slight degree, it is understood to contain the so-called antirachitic vitamin. Cocoanut oil seems to possess the antirachitic factor in still less degree than butter, and with less uniformity. Both of these substances are greatly deficient in the antirachitic factor, however; and so far as now known, cod liver oil is the only substance containing this factor in such a large degree as to enable its use as a specific for rachitis.

According to the present invention, feeds for animals, and food products for man, and medicines for man and animals, may have imparted to them the antirachitic factor, or may be rendered antirachitically active by subjecting them to the action of actinic rays and especially the rays in the region of the ultra violet rays of the spectrum, such as emanate from a mercury vapor lamp. The activation is very readily effected by means of a quartz mercury vapor light, though the open flame carbon arc, or other source of light may be employed in effecting the activation.

As an example, olive oil may be antirachitically activated by moderate exposure to the action of the rays of a quartz mercury vapor lamp rich in ultra violet rays, and, generally spoken of, as ultra violet light. This may be accomplished, for illustration, by placing in a shallow dish, having a length of about ten inches and a width of about five inches, olive oil to a depth of about one-eighth of an inch, and exposing the oil to the action of the rays of a Cooper-Hewitt quartz mercury vapor lamp, type BY, for about thirty minutes, such lamp having an arc of about one and one-half inches initially, and operated by current at about forty-eight volts and a current of about four amperes, the source of light being placed at a distance of about two feet from the oil. Thus treated, the oil acquires an antirachitic strength substantially equal to that of cod liver oil.

The length of time of the exposure to the rays may vary greatly, depending upon the volume of the product being treated, the manner in which it is exposed, the intensity of the light, and the distance of the material from the light. It should be pointed out, however, that an over exposure is possible. For example, if treatment under the conditions mentioned above is continued for a period of seventeen hours, it is found that the olive oil, at first activated by the moderate treatment, changes its physical and chemical character, and loses the antirachitic factor. It has been found, also, that cod liver oil treated under such exposure for a period of seventeen hours loses its antirachitic factor. In practice, the exposure will be properly regulated to produce the desired effect of imparting the antirachitic factor to the material being treated, it being understood that the intensity of the light employed, the time of exposure, and the various factors entering into the treatment will vary with the method employed.

Various foods for man and animals may be antirachitically activated in the manner suggested above. This applies both to solid and liquid foods, including those comprising proteins, carbohydrates and fats. Fats and oils activated in this manner afford a very convenient medium for introducing activated material into various foods, or rations, including solid foods, oils, salad dressings, etc. Also, activated fats afford a convenient medium for introducing the activated material into medicines; or, selected activated fats may be obtained in the form of an extract, or in condensed form, and used in tablets, or in capsules, for medicinal purposes.

In general, the process is applicable to the treatment of organic substances having food or medicinal value. Examples are: meat, or muscle; cereals, grains and seeds; hulls, brans; oils and fat of various kinds, such as corn oil, peanut oil, cocoanut oil, cottonseed oil, oleo oil, olive oil, lard, tallow, etc.; and grains, roughage, or mixtures thereof may be irradiated and have imparted to them the antirachitic factor. In the same manner, dog biscuit, feed for chicks, and various other feeds for animals may be activated. It is practicable, of course, to activate one material of a ration, and mix the activated material with other unactivated materials of the ration. For example, corn oil, or other oil, may be activated and mixed with a feed for cows, or other animals.

Butter, or butter fat, may be activated without injuring the vitamin A contained in the butter. This may be done by maintaining the butter in a inert atmosphere, such as an atmosphere of carbondioxide, while the butter is being irradiated by means of the ultra violet rays. Again, milk may itself be treated and activated to a certain extent, or milk, as well as artificial baby foods, may have admixed therewith an activated oil, or other activated substance. The artificial baby foods may themselves be directly exposed to the action of ultra violet rays and be thus activated, if desired. The same is true with regard to breakfast foods, cereals, etc.

In the oils and fats, it appears that the unsaponifiable constituents may be highly activated; and these unsaponifiable lipoids may be separated from the saponifiable fats.

The activation of the lipoids may be effected either before or after separation from the saponifiable fats or constituents. For example, olive oil may be activated by subjecting it to the action of the ultra violet rays; the activated oil may be saponified by boiling it thirty minutes in a 20% solution of KOH in alcohol; the material may then be diluted with water; the unsaponifiable substances may be extracted with ether; the extract in ether may be washed; and the ether solution may be mixed with food and the ether evaporated, or allowed to evaporate. The result is to impart to the food the antirachitic property. If desired, the ether may be evaporated from the solution, and thereby the activated lipoid may be obtained in the form of a waxy material. This may be used in suitable capsules, or may be compounded with other materials into capsule form, or may be used in any suitable manner for medicinal purposes. In this manner, the activated material may be obtained in concentrated form.

On the other hand, if desired, the lipoids may be separated from the olive oil by any suitable method, and the lipoids may then be activated by exposure to ultra violet rays. Other substances relatively rich in lipoids may be employed for the purpose of obtaining extracts, or concentrated activated material. For example, brains obtained from slaughter houses may be mixed with plaster Paris, thus producing a friable compound; the unsaponfiable lipoids may be extracted from the mass with acetone; the acetone may be evaporated and the unsaponifiable lipoids cause to separate out, they may then be dissolved in alcohol and boiled with a solution of a caustic base, such as KOH or NaOH, for thirty minutes; the product may be washed or diluted with water and the lipoids extracted with ether; the ether solution may be mixed with food and the ether caused to evaporate, or the ether may be separately evaporated and the unsaponifiable ingredients obtained as a waxy material. The activation may be produced either by subjecting the brain matter to the action of the ultra violet rays or by subjecting the extracted unsaponifiable constituents to the action of ultra violet rays.

It may be stated here that the activated material maintains its activated condition for prolonged periods; and while it has not been determined what rate of loss, if any, may occur, the activated condition is maintained for a sufficient length of time for the practical purposes suggested herein.

Oleomargarine may be activated by direct treatment with the ultra violet rays, or it may have supplied to it the antirachitic principle by activating an oil, such as olive oil, and mixing the activated oil with the oleomargarine; or, if desired, concentrated activated material may be obtained in the manner suggested above, and supplied to the oleomargarine.

Various other methods of making practical use of the invention will readily occur to those skilled in the art. It was found, for instance, that a ration of millet seed 84, casein 12, and salts 4, when subjected to treatment by ultra violet light for thirty minutes, under substantially the conditions mentioned above for treating olive oil was greatly improved in its power to support growth in the rat. It has been found, also, that improved growth and proper formation of bone occur concurrently as the result of activation of the food in the manner herein described. It has been definitely established that the irradiated ration, or irradiated food, will serve to cure rachitic bone. It has been established, both chemically and by bone appearance, that the calcium metabolism may be maintained at the normal, by use of activated foods or materials, under various conditions when it is difficult for the animal, for one reason or another, to maintain the proper growth and structure of the bone without such aid.

While I do not rest the present invention upon any theory, I give it as my belief that the effect of activating food materials is to cause the activated constituent to emit, in the body, rays which perhaps are of invisible character, and which, in some manner, cause the calcium depositing cells of the bone to function properly. In this respect, the activated material may emit rays somewhat analogous to the manner in which activated zinc sulphide emits, in the dark, rays which excite the retina, and thus are visible. It is, however, not excluded that the effect may be produced by a structural rearrangement in some compound or compounds contained in the food materials.

It has been found that lard can be activated in the same manner as the various oils can be activated. Bone known to be definitely rachitic shows a more or less characteristic histological bone picture. On the other hand, normal bone produces a picture distinct from that of the rachitic bone. The rachitic bone may be restored to the normal by feeding the animal a properly activated ration.

A ration of corn 33, wheat 33, wheat gluten 15, gelatine 15, sodium chloride 1 and calcium carbonate 3 produces in rats, within a period of a few weeks, distinct rachitic conditions. On the other hand, such a ration, when properly activated, or supplied with activated material, will maintain the proper growth and bone structure.

From the description and statements thus far given, it will be understood that the invention is important from various standpoints. The use of an activated feed for chickens, cattle, and other stock, would have a two-fold object: It would enhance the economical production of pork, beef and chicken, together with eggs, milk and the various products of milk; and it would furthermore increase the antirachitic content of these products, and thus benefit man directly.

For man, this invention has particular value. For the adult, solid foods, such as manufactured breakfast foods, flour, meals, dry fruits, and fats and oils, such as cocoanut oil, lard, olive oil, cottonseed oil, peanut oil, oleo oil, etc. may be directly activated and used. For the pregnant and lactating mother, usually closely confined indoors, and to a lesser degree, for the growing boy or girl such activated foods will be particularly beneficial. By the general use of such activated food by the lactating mother, the antirachitic properties of milk will be increased, thus minimizing the early incidence of rickets in the child, and obviating the various defects in the child which arise from a rachitic condition. Again, the child itself may be fed on modified milk foods, grain extracts, or other preparations, which have been activated by light, or which have had admixed therewith activated substances; or, if desired, the child may be given activated oils in medicinal doses. These activated oils have the advantage of being practically tasteless, and without objectionable odor; and suitable flavors may be added to good effect.

In addition to the value of the invention in connection with infant foods and butter substitutes, the invention finds a most useful application to medicinal preparations. Activated oils, or activated unsaponifiable constituents thereof, may be used for such purpose, as suggested above.

The time and manner and exposure of the food or material to the action of the actinic rays must be varied with the nature of the material exposed, and various other factors, as suggested above. These factors will readily be determined by those skilled in the art. in view of the explanation given above; and in actual practice, activated materials may be subjected to actual test, from time to time, to insure proper manufacture. Fats spread out in a thin layer on conveyor belts may be exposed to the action of light; liquid materials may be allowed to flow in films while being subject to a light treatment; or liquids, such as oils, may be exposed by spraying them through a zone acted upon by the actinic rays. In this connection, it is to be borne in mind that the ultra violet rays do not pass readily through glass; and where vessels are employed through which rays are to pass, such vessels should be of quartz, or of very thin glass.

The oils mentioned above are liquid glycerides which are fairly rich in unsaponifiable lipoids. These oils constitute an important subdivision of the fats.

The palatability of the treated foods may be injured or destroyed by undue prolongation of the irradiation. This is to be avoided.

Sunlight, of course, contains ultra violet rays, but it is not available practically for the production of the antirachitic principle. Artificial light rich in the rays of the ultra violet region of the spectrum is necessary. Roentgen rays (X-rays) have a wave length definitely below that which is necessary in the process, and thus are not suitable for use in the process.

In dealing with fats and oils, such as olive oil, maximum activation can be effected in a period of about thirty minutes by the treatment mentioned above. The treatment may be prolonged for a considerable period, under such conditions, without injury, but if unduly prolonged and if too intensive, the antirachitic principle will be destroyed.

Apparently, in the case of fats (including oils) some changes ultimately occur in the non-activated constituents which neutralize, or destroy, the antirachitic principle previously produced by the treatment in the unsaponifiable fats. On the other hand, if the lipoids be separated before treatment, it is found that the treatment can be prolonged through a period of many hours without destroying the antirachitic principle. This seems to be true, also, of such substances as corn meal. It follows that in the case of the fats (including oils), especially, care should be taken to avoid over-irradiation.

Eggs, more particularly the yolks of eggs, may be activated antirachitically by the process described; also, as indicated above, cholesterol, before or after separation from other fats, may be activated antirachitically by the process described.

What I regard as new, and desire to secure by Letters Patent, is:

1. The process of imparting antirachitic properties to organic substances of dietary value (for example carbohydrate foods, fats, oils, protein foods, or composite foods), which comprises subjecting the same to the action of ultra-violet rays, such as are produced by a quartz mercury vapour lamp, for a period sufficient to effect antirachitic activation but so limited as to avoid subsequent substantial injury of the antirachitic principle.

2. The process set forth in claim 1 as applied to oils and fats containing unsaponifiable lipoids.

3. The process set forth in claim 1 as applied to naturally liquid glycerides.

4. The process set forth in claim 1 as applied to olive oil.

5. Naturally deficient (in the antirachitic factor) food substance antirachitically activated in accordance with the process set forth in claim 1.

6. The naturally deficient (in the antirachitic factor) liquid glycerides containing constituents antirachitically activated in accordance with the process set forth in claim 1.

7. Olive oil antirachitically activated in accordance with the process set forth in claim 1.

8. The process of imparting antirachitic properties to organic substances of dietary value (for example carbohydrate foods, fats, oils, protein foods, or composite foods), which comprises subjecting the same to the action of ultra-violet rays, such as are produced by a quartz mercury vapour lamp, for a period sufficient to effect antirachitic activation but so limited as to avoid subsequent substantial injury to either the antirachitic principle or the palatability.

HARRY STEENBOCK.

UNITED STATES PATENT OFFICE

DAVID BASKY, OF DULUTH, MINNESOTA, ASSIGNOR, BY MESNE ASSIGNMENTS, TO THE INTERNATIONAL HONEY-BUTTER CORPORATION, OF CLEVELAND, OHIO, A CORPORATION OF OHIO

FOOD PRODUCT AND PROCESS OF PRODUCING THE SAME

No Drawing. Application filed January 29, 1930. Serial No. 424,451.

This invention relates to a novel food product and process of producing the same, and comprises an admixture of honey and butter.

It is well known that honey and butter have heretofore been mixed to form a new food product, but in each instance where this has been done desirable characteristics of the butter have been lost during the mixing process, and it is the principal object of my present invention to provide a product containing butter and a substantial quantity of honey united into a homogeneous mass which resembles commercial butter and has the same relative density thereof so that my honey and butter product may be cut, wrapped, and packed in the standard machines available for that purpose.

Another object of my present invention is to provide a process for the admixing of honey and butter in the least time possible, and with the standard machines available to the creamery trade.

Further objects and advantages of the invention will become apparent in the following description thereof.

My product consists only of honey and butter, and the term honey is used to include natural bees' honey, or a product artificially prepared as a substitute therefor; and similarly the term butter is used to include butter and butter substitutes such as are common on the market.

The proportions of the materials employed are not material, but I have found that an excellent product may be produced from 50% honey and 50% butter.

In the manufacture of the product the honey, preferably in liquid form, is placed in a hot well and heated to a temperature of 120° to 130° F., and is then placed in a vacuum pan or condenser for removing moisture and air, and wherein the honey will boil at a lower temperature ranging from 90° to 127° F. under vacuum, but the temperature in the vacuum pan is held not higher than 127° F., as at higher temperatures the honey would lose its flavor or become burned. While in the vacuum pan some of the air and a small percentage of moisture will be evaporated, approximately 7%, which is found to result when ultimately mixed with the butter in a better commercial and a more palatable product. The honey is then removed from the pan and allowed to cool to preferably 80° to 90° F.

This vacuum treatment is necessary in order to obtain a better commercial product, since by such treatment, the viscosity of the honey is increased because of the removal of water and air therefrom as pointed out hereinbefore; also its granulating temperature is reduced in proportion to the amount of water removed, whereby, when mixed with the butter, the product may be kept at a low temperature without granulation occurring; such as when in cold storage or in refrigerated cars during shipment.

It has been found that for best results in the preliminary preparation of the butter great care must be taken to maintain same in a cool state, and which is preferably continued throughout the mixing process. Therefore the butter is kept preferably at a temperature of approximately 40° to 50° F. and is first mixed slowly in any suitable appliance such as a rotary mixing machine, when, due to the said temperature of the butter while being mixed, a part of the contained moisture is separated from the butter. The speed of the machine is then increased, when the butter in its changed condition will again take up the water, putting it in condition to receive the honey; this whole operation of preparing the butter consuming about one to three minutes.

The honey is then added to the cool butter, preferably in equal amounts, and mixed slowly until the product takes on a kernelly form, when, upon continued mixing, it will coagulate to a semblance of commercial but-

ter. This mixing operation will consume about one or two minutes. The speed of the mixer is then approximately doubled and the mixing continued, when the outside of the bowl is then quickly tempered as with a hose or spray of warm water, or if mixed in a jacketed bowl flushing same quickly, or otherwise suddenly warming if preferred, which will release any material adhering to the bowl, and insure a wholly uniform admixture, and also prevent too great an amount of air being incorporated therein. After mixing a few minutes longer the honey and butter become thoroughly comingled whereby the particle of honey is surrounded by the particles of butter, and the product is taken out at a temperature of about 60° to 70° F. preferably, when it may be placed in boxes in refrigerating rooms, and subsequently cut and wrapped in a manner similar to that of commercial butter.

During the entire process the butterfat is not melted which is a very essential feature in the novel method, as well as the fact that the finished product has the same relative density as butter, whereby a pound of the product displaces the same space as a pound of butter and consequently the same machines may be used for wrapping and packing the product.

From the foregoing it appears that there has been produced a product consisting of an emulsion of liquid honey and butter in which the butter is the dispersing or continuous phase and the honey is the dispersed or discontinuous phase. In other words, it is an emulsion of honey in butter, or one in which the honey particles are surrounded by butter.

Having thus described my invention, what I claim and desire to secure by Letters Patent, is:

1. The herein described method of mixing extracted honey and butter comprising first preparing the honey by heating same in partial vacuum to avoid over-heating, then partially cooling and uniting with butter which had been separately slowly mixed until it lost a portion of its contained moisture and then rapidly mixed until it again absorbed said moisture, then mixing the honey and butter until it assumes a fluffy consistency, when the conclusion of the working operation is governed by the desired relative density.

2. The herein described method of preparing a mixture of extracted honey with butter comprising; first, heating the honey in partial vacuum to increase its viscosity and reduce the air and moisture content without detriment thereto; separately slowly stirring the butter until it has lost a portion of its contained moisture and then rapidly stirring same until it again absorbs said moisture; and then mixing the honey thus prepared and the butter thus prepared at a temperature below the melting point of butter fat.

3. An edible emulsion consisting of butter and liquid honey wherein the honey constitutes the discontinuous phase and the butter the continuous phase.

4. An edible emulsion consisting of butter and liquid honey wherein the honey constitutes the discontinuous phase and the butter the continuous phase, said product having substantially less moisture than the combined moisture content of the original ingredients.

In testimony whereof I affix my signature.

DAVID RASKY.

Patented May 30, 1933 **1,911,882**

UNITED STATES PATENT OFFICE

PHILLIP E. CRANE, OF MIDDLEBURY, VERMONT, ASSIGNOR TO CRANE HONEY INCORPORATED, OF WASHINGTON, DISTRICT OF COLUMBIA, A CORPORATION OF DELAWARE

FOOD PRODUCT

No Drawing. Application filed April 30, 1930. Serial No. 448,790.

An object of my invention is to provide a food product which will utilize honey that is so desirable for food which will increase the availability of honey and its attractiveness to consumers, and in particular to provide such product available for use in the form of a spread.

My invention consists in whatever is described by or is included within the terms or scope of the appended claims.

In what at the present time I consider the most desirable and advantageous embodiment of my invention, I combine apricot and in a dried or dehydrated form with honey in granulated form. A very good proportion is ten parts of dried apricots to ninety parts of honey, but, of course, I do not confine myself to that proportion. That proportion enables a large quantity of honey to be used and yet the comparatively small proportion of apricot gives the modifying effect on the honey which is important as affecting its sweetness and taste and giving the product the mechanical and other properties which the product by extensive use on the market is shown to possess. The product by reason of the presence of the apricot does not have the stickiness and fluidity of honey, and, therefore, the product is convenient to handle, especially when used as a spread because it does not tend to run and yet it may be readily spread or applied to the surface of a slice of bread for example. The dried apricot has sufficient toughness to overcome or diminish the natural fluidity of honey when the two are thoroughly mixed and in effect become a homogeneous product. Though having the desired degree of toughness, it nevertheless is sufficiently stretchable under spreading pressure to render it available as a spread.

In order to bring about the desired intimate mixture of the honey and dried apricot, I subject them to a milling or grinding process as by the action of disks or rolls.

Other dried or dehydrated fruits, berries, vegetables and nuts may be used in place of apricot or combined with the apricot and the honey.

A very important consideration in the production of a food product embodying my invention is that no heating or cooking is required to render the product entirely available as a spread. Apricots notably, and other fruits and vegetables contain potent materials that are valuable in the human system which are injured or destroyed when they are heated or cooked for food.

What I claim is:—

1. The method of forming a food spread which comprises intimately admixing substantial proportions of dried fruit and granulated honey to produce a homogeneous body which is characterized by its adaptability for being readily spread and the fact that it will not ferment under the atmospheric and temperature conditions to which food spreads are normally subjected in marketing.

2. The method of forming a food spread which comprises intimately admixing substantial proportions of dried apricot and granulated honey prior to any substantial heating thereof so that the enzymes and food values present in natural unheated honey will be present therein, the admixture being effected to such extent as to form a homogeneous body which is characterized by its adaptability for being readily spread and its freedom of objectionable stickiness.

3. The method of forming a food spread which comprises intimately admixing substantial proportions of dried apricot and granulated honey by milling or grinding the same to produce a homogeneous body which is characterized by its adaptability for being readily spread and the fact that it will not ferment under the atmospheric and temperature conditions to which food spreads are normally subjected in marketing.

4. A food product comprising granulated honey and dried fruit in substantial proportions as a homogeneous mixture of the consistency of a spread which is characterized by being capable of being readily spread and the fact that it will not ferment under the atmospheric and temperature

conditions to which food spreads are normally subjected in marketing.

5. A food product comprising granulated honey and dried apricot in substantial proportions as a homogeneous mixture of the consistency of a spread which is characterized by being capable of being readily spread and the fact that it will not ferment under the atmospheric and temperature conditions to which food spreads are normally subjected in marketing.

6. A food product comprising an intimate admixture of approximately 10% of dried fruit with 90% of granulated honey, which honey contains the enzymes and food values present in natural unheated honey, and the intimate admixture being such that it is in the form of a substantially homogeneous body having the consistency of a spread which is characterized by being capable of being readily spread and the fact that it will not ferment under the atmospheric and temperature conditions to which food spreads are normally subjected in marketing.

7. The method of forming a food spread which comprises intimately admixing dried fruit and granulated honey by milling or grinding the same at substantially atmospheric temperature to produce a homogeneous body, the honey being in excess of the dried fruit and the admixing being effected prior to any substantial heating of the honey so that the enzymes and food values present in natural unheated honey will be present in the product, the admixing being effected to such extent as to form a homogeneous body which is characterized by its adaptability for being readily spread and the fact that it will not ferment under the atmospheric and temperature conditions to which food spreads are normally subjected in marketing.

In testimony whereof I hereunto affix my signature.

PHILLIP E. CRANE.

Patented July 2, 1935 **2,007,108**

UNITED STATES PATENT OFFICE

2,007,108

MEDICINAL PREPARATION

Harry Bresnick, New York, N. Y.

No Drawing. Application October 8, 1934,
Serial No. 747,477

8 Claims. (Cl. 167—81)

This invention relates to the production of a new medicinal preparation containing fish-liver oils of high vitamin content in which the nauseous and objectionable odor and taste of these oils are effectively masked, and which preparation remains stable over a long period of time. The invention furthermore embraces a novel process of producing the new medicinal preparation.

This application is a continuation-in-part of my application Serial No. 710,109, filed February 7, 1934.

Medical science has acknowledged for a long period of time the dietary values of vitamins, and particularly the curative and prophylactic characteristics of the vitamin A. Until recently, the cod fish was known to be the richest source of vitamin A, this fish having the peculiar ability to concentrate this vitamin in its liver oil. In recent times, it was discovered that the halibut surpassed the cod as a source of vitamin A, and that the liver oil of the former was from 100 to 200 times as rich in vitamin A as that of the latter.

In the development of vitamins in the field of medical science, cod-liver oil had been treated to concentrate the vitamins A and D found therein, and these concentrated sources of vitamins were embodied in capsule or tablet form. This mode of obtaining the desired vitamins proved more palatable than the taking of natural cod-liver oil. However, since these vitamins seem to be associated preponderantly with fats in nature, there appeared to be a heavy loss in potency and activity of these concentrates unless they were accompanied by fats. For this reason, natural cod-liver oil was generally prescribed, so that no loss would take place in the digestive absorption of the needed vitamins.

The discovery of a concentrated source of vitamin D in a solution of irradiated ergosterol in oil made possible the control of this vitamin in diets. This was particularly simple in view of the stability of the above solution which rendered it adaptable to be incorporated in various dosages in canned foods, milk, bread, and other foodstuffs. Although halibut-liver oil is as much as 200 times stronger in its vitamin A content than cod-liver oil, the former is only several times greater in its vitamin D content than the latter. The addition of irradiated ergosterol in oil to vitamin sources supplies the vitamin D content in any desired proportions. Although the vitamin D content remains fixed in concentrated vitamin sources derived from the fish-liver oils, this is not the case with the vitamin A content, which is readily subject to oxidation and deterioration.

It is the object of the invention to overcome the above deficiencies, that is, to provide a palatable and readily digestible medicinal preparation having the desired vitamin content in which suitable fats are re-introduced in combination with the vitamins to render the compound easily digestible and to effectively preserve the fish oil with its vitamin A potency for a long period of time.

The use of fish-liver oils of high vitamin content presents many other difficulties. In view of the nauseous and objectionable taste of these oils, great difficulty is experienced in administering them, especially to infants and children. In the attempt to make these oils, particularly halibut-liver oil, more pleasant in appearance, the oil is refined to impart a light attractive color thereto, and thereby a great portion of its therapeutic effect is sacrificed. Furthermore, these oils are fed to children in minute dosages, and, for instance, when a three minim dose is fed to a child on a spoon, or in a bottle with a nipple, or in a glass, it is impossible to know accurately the amount of the oil taken by the child, since some of the fat adheres to the glass or spoon.

Another difficulty attending the keeping of the fish-liver oils is the separation of the heavier stearine which forms a small percentage of these oils, this stearine falling and adhering to the bottom of the vessels containing the oils. A substantial portion of the vitamin and other therapeutic value of the fish-liver oils is contributed by these stearines. A simple shaking of the vessel without heating is not effective in placing the component fats in solution, and thereby the medicinal effect of the oils is diminished.

It is the object of the instant invention to overcome all of the above mentioned difficulties. By embodying suitable masking ingredients with the preparation containing a hard fat in combination with the fish-liver oils, it is possible to hide completely the taste and odor of the latter. I have found that the addition of suitable flavoring and sweetening ingredients to the mixture of the fish-liver oils bound in the hard fat renders the composition highly palatable and capable of easy feeding to children. Furthermore, since the final product in accordance with the invention is a solid in the nature of a confection, the color of the fish-liver oils which are

originally embodied in the composition is immaterial and the crude halibut-liver or other fish-liver oil may be used, with its full strength vitamin content. The incorporation of specific quantities of the fish-liver oil in the mixture in which the amounts of the other ingredients are fixed, and the subdivision of the complete mass into a predetermind number of units, serve to determine accurately the individual dosages of the fish-liver oil. Also, the homogeneous character of the product according to the invention assures a uniform dispersion of all of the constituents of the fish-liver oils as well as of all of the other ingredients. Thus, no separation of stearine from the other constituents of the fish-liver oils takes place.

It is a further object of the invention to produce a new concentrated medicinal composition of matter containing fish-liver oils, which preserves indefinitely the therapeutic properties of these oils, and which prevents the rancidity thereof. In the composition, according to the invention, the fish oil is preserved for a long period of time without deterioration and with no diminution of the vitamin A potency.

I have found that a substantially anhydrous composition of a vegetable fat such as cocoa butter with fish-liver oils keeps for a long time without deterioration and with no loss of the vitamin content, particularly vitamin A, which is oxidizable. Although I have met with partial success by using different dehydrated vegetable fats, I have found that cocoa butter is the most suitable, and that results nearly as satisfactory may be obtained by the use of palm-kernel or coconut stearines. In order to render the composition stable, I have found that the moisture content thereof should be maintained at a minimum. An upper limit of ½% of moisture based upon the complete mass of the composition produces a highly stable and satisfactory product. A smaller moisture content results in even more stable product. Although the moisture content may exceed ½% without sacrificing the full advantages of the invention, I have found that a moisture content of more than 1 and ½% renders the composition unstable within a comparatively short period of time, which renders it impractical from a commercial viewpoint.

Although the combining of the vegetable fat in the form of cocoa butter with the fish-liver oils in such a manner that the composition is substantially anhydrous, whereby the fish-liver oils are effectively preserved against deterioration, results in a useful product, the full utility thereof as a medicinal preparation is not realized until one or more masking ingredients are added to hide the objectionable taste and odor of the fish-liver oils. I have found that a sweetening in combination with a flavoring are most satisfactory for this purpose.

Since the product according to the invention is limited in its moisture content, the most practical form of sweetening is sucrose. The sweetening should be preferably crystallizable. However resort may be had to any known sweetening, and I have used cane-sugar with complete success.

Any desired flavoring may be employed, preference being shown to flavorings having the least moisture and which in themselves are fairly stable, such as spices, barks, powdered and essential flavorings. Cocoa and a terpeneless orange oil in combination are excellent as flavorings. The cocoa of the Arriba type is preferable of an amount about 15% of the total weight of the homogeneous mass. Six minims of the terpeneless orange oil per pound of the finished product is adequate, this ingredient furthermore possessing in itself advantageous therapeutic properties. Also, any other stable dry medications may be added, as well as milk fats and solids. I have found grain honey a satisfactory flavoring.

Another ingredient which may be added to the composition of vegetable fat with fish-liver oils, with or without the sweetening and flavoring ingredients, to produce an improved composition is lecithin. A slight amount of this product, about ½% of the finished mass, is effective as a binder for the fish-liver oils of lighter specific gravity with the heavier oils and fats in the cocoa butter or other hard fats. The lecithin furthermore tends to retard the hydrolysis of fats and prevents the formation of free fatty acids, and it also aids in the digestive processes in the oxidation of the fatty acids.

The product according to the invention is prepared in the following manner:

The vegetable fat such as cocoa butter, the sweetening and the flavoring are combined in suitable proportions, specific examples of which are set forth below, and are continuously agitated in a conching machine in a dry hot room until a moisture test of the batch indicates a moisture content at least in no great excess of ½%, although reasonably satisfactory results may be obtained with an upper limit of the moisture content in the vicinity of one and one-half percent. Thereupon the batch is gradually cooled to about 100° F. The fish-liver oil or oils may then be added to the batch and thoroughly stirred therein to form one homogeneous substantially anhydrous mass. If lecithin forms a part of the composition, it is first mixed with the fish-liver oils and the resulting mixture is added to the batch of other ingredients.

This entire mixing process may be conducted in vacuo.

As soon as possible after the thorough incorporation of the fish-liver oils, with or without lecithin, in the mass, the temperature thereof is reduced to about 84° F., and poured into molds. The molds are placed in a dry atmosphere at a temperature of about 50° F. until the molds are set. I prefer, for the final physical form of the product, small square tablets, about 180 to the pound, each wrapped in tin foil. It is also commercially practical to mold the product in squares, 12 or more to a block, with deep shoulders between the squares so that the individual squares may be broken off easily, the whole block also being wrapped in tin foil. Each square is designed to contain a therapeutic dosage. Of course any number of other forms of the product are practical commercially; the composition in its plastic state incorporating a high percentage of fish-liver oils may be formed into balls and coated or placed in capsules.

The atmosphere in which all operations are conducted should be dry to prevent excessive moisture being absorbed by the mass; however I do not confine myself to a specific humidity so long as the complete operation can be conducted within the moisture range suggested.

While one may combine cocoa butter with sucrose and a flavoring and with slight heat form a solid mass, there is a decided advantage in long "conching" of the cocoa butter and

sucrose, since the smaller the sucrose crystals, the more cocoa butter may properly be added. Also conching for a lengthy period in a dry warm atmosphere diminishes the moisture content of the mass. While the ingredients I prefer may actually only require 25% of cocoa butter, I much prefer about 40%, as this enables the use of a larger percentage of fish-liver oil with safety; and a higher percentage of cocoa butter to the total mass makes for a firmer, more homogeneous mass.

About 7% of fish-liver oils calculated upon the weight of the finished mass may be incorporated in the composition without any difficulty being encountered in the masking of the odor and the taste thereof by the masking ingredients. Such a proportion of fish-liver oils also results in a stable composition for a long period of time. I have found that amounts of fish-liver oils higher than 10% render the masking thereof difficult by the sweetening and flavoring ingredients mentioned above. A highly practical composition is formed by a mixture of 35–40% vegetable fat such as cocoa butter, 15% flavoring, 40% sweetening and 10–5% fish-liver oils. These percentages may be varied in accordance with the different strengths of the ingredients which enter into the composition.

Having described my invention, what I claim is:

1. The process of preparing a concentrated medicinal composition which comprises thoroughly admixing and substantially dehydrating a vegetable fat, a flavoring, and a sweetening in the presence of heat in a dry atmosphere to the extent that the moisture content thereof is substantially no greater than one and one-half percent of the finished mass, incorporating fish-liver oil in said admixture to form a homogeneous mass, and permitting said mass to cool and solidify.

2. The process of preparing a concentrated medicinal composition which comprises heating and thoroughly admixing cocoa butter, a flavoring and a sweetening, substantially dehydrating said admixture to the extent that the moisture content thereof is substantially no greater than one and one-half percent of the finished mass, incorporating fish-liver oil in said admixture to form a homogeneous mass, and permitting said mass to cool and solidify, all of said steps being carried out in a dry atmosphere.

3. A substantially anhydrous edible medicinal preparation comprising an intimate mixture of an edible dehydrated hard vegetable fat and a fatty material having a high vitamin content subject to deterioration, said mixture having a moisture content substantially no greater than one and one-half percent of the mass.

4. A substantially anhydrous edible medicinal preparation comprising an intimate mixture of cocoa-butter and fish-liver oil having a high vitamin content subject to deterioration, said mixture having a moisture content substantially no greater than one and one-half percent of the mass.

5. A substantially anhydrous edible medicinal preparation comprising an intimate mixture of an edible dehydrated hard vegetable fat, a fatty material having a high vitamin content subject to deterioration and lecithin, said mixture having a moisture content substantially no greater than one and one-half percent of the mass.

6. A substantially anhydrous edible medicinal preparation comprising an intimate mixture of an edible dehydrated hard vegetable fat, fish-liver oil having a high vitamin content subject to deterioration and at least one additional ingredient for masking the taste and odor of the fish-liver oil, said mixture having a moisture content substantially no greater than one and one-half percent of the mass.

7. A substantially anhydrous edible medicinal preparation comprising an intimate mixture of an edible dehydrated hard vegetable fat, fish-liver oil having a high vitamin content subject to deterioration, a sweetening and a flavoring, said mixture having a moisture content substantially no greater than one and one-half percent of the mass.

8. A substantially anhydrous edible medicinal preparation comprising an intimate mixture of cocoa-butter, fish-liver oil having a high vitamin content subject to deterioration, cocoa and a sweetening, said mixture having a moisture content substantially no greater than one and one-half percent of the mass.

HARRY BRESNICK.

UNITED STATES PATENT OFFICE

2,022,464

VITAMIN CONCENTRATE

Lloyd A. Hall, Chicago, Ill., assignor of one-half
to Carroll L. Griffith

No Drawing. Application February 17, 1933,
Serial No. 657,311

3 Claims. (Cl. 167—81)

This invention relates to a process of incorporating vitamin concentrates having an oil base into food products and particularly to the emulsification of vitamin concentrates.

Vitamin concentrates having an oil base and either synthetic or extracted from natural sources, have been sold previously. The oil base may be cottonseed, corn, coconut or other edible oil, or it may be naturally occurring fish oils such as cod, salmon or halibut liver oils. In this form the incorporation of such concentrates in food products is not entirely satisfactory, because the oil base of the concentrate makes uniform mixing throughout the food product difficult.

By means of this invention vitamin concentrates, particularly those containing vitamin D or vitamin A, are prepared which may be incorporated readily in food products where such concentrates will be useful, for example: bread, milk, butter, margarine, cheese, ice cream, salad dressings, cereals and other food products. In accordance with this invention the oil base vitamin concentrate is emulsified to produce a product which is very palatable as a food or medicine and which may easily and uniformly be incorporated into food products.

The emulsion may be prepared by using an emulsifying agent such as gum acacia, gum tragacanth, India or Karaya gum, gelatin, pectin, starch paste, Irish moss, agar agar, casein, egg yolk or albumin. The emulsifying agent is mixed with the oil base vitamin concentrate, and its hydrogen ion concentration is so adjusted that the value for the finished emulsion will be pH 5.5 to 6.0, by adding water containing in solution a mild alkali such as sodium bicarbonate or a weak acid such as citric or acetic acid, according to whether the original pH is above or below the desired range.

For example an emulsion may be made by adding to one quart of oil base vitamin concentrate (for example irradiated ergosterol or a powerful cod liver oil extract) 7 ounces of gum acacia, 1 ounce of gum tragacanth and 1 quart of water containing sodium bicarbonate in an amount sufficient to adjust the pH to 5.5 to 6. The emulsion is prepared by placing the gums in a dry mixing receptacle and pouring the vitamin concentrate upon them while mixing it with the gums, for example by a mechanical agitator. The sodium bicarbonate solution is then prepared and one pint is added to the gum-vitamin mixture separately, and while rapid agitation is taking place. The mixture is then stirred and beaten until it has assumed a smooth consistency, after which the remainder of the water solution is added and the mixing continued briskly for 30 minutes. It is desirable, however, to cease mixing about 4 times during this interval, for about 2 minutes at each time. That is, the 30 minutes should be divided into periods of about 7½ minutes of beating with 2 minutes intermission before the next beating.

The pH of the mixture is then tested and additional soda or a weak acid solution is then carefully mixed in to adjust the pH value to 5.5 to 6.0. After the product has stood for one hour it is preferred to gently stir it for a few minutes and then run it through a colloid mill to further perfect the emulsion by more minute disintegration and colloidizing of the oil globules.

If it is desired to use the emulsion directly for internal administration either as a medicine or as a material part of a food, suitable essential flavoring matter such as orange, lemon, lime, strawberry, pineapple, or cherry flavoring oils may be added in the form of a syrup to replace part of the water. If it likewise is desired, a suitable color may be dissolved in part of the water to produce a product of a desired color.

For example, in the preceding mixture 1 pint of the quart of water may be replaced by 1 pint of ordinary syrup (32° Baumé), 2 ounces of cold pressed California orange oil, 1/16 ounce certified Sunset yellow color and 1/16 gram of certified Ponceau 3R.

It is preferred to use the uncolored and unflavored emulsion for incorporation into food products. It mixes smoothly and uniformly in the manufacture of bread, milk, ice cream, butter, peanut butter, margarine, salad dressings, cheese, and the like, and does not produce a noticeable flavor or odor. For example in bread, the emulsion may be mixed with the water and then added to the dough, whereas with former vitamin concentrates it was necessary to incorporate them in the shortening which was unsatisfactory and not efficient.

In the case of ice cream or butter, the vitamin concentrate may be mixed thoroughly with the cream or milk and thereafter the regular process of manufacture followed. The vitamin concentrate is readily incorporated in milk or cream simply by mixing.

It is preferred to use a vitamin concentrate containing 6,000 A. D. M. A. (American Drug Manufacturers) units per gram. A vitamin concentrate of this strength will produce an emulsion from 20-40 times more potent than cod liver oil. Synthetic vitamin concentrates in

vegetable oil bases may also be used when desired.

The foregoing detailed description has been given for clearness of understanding only, and no unnecessary limitations should be understood therefrom, but the appended claims should be construed as broadly as permissible, in view of the prior art.

What I claim as new and desire to secure by Letters Patent is:

1. As a composition of matter, an emulsified vitamin D concentrate, said emulsion containing 2700 A. D. M. A. units per gram, said emulsion containing as emulsifying agents approximately 1 part of gum tragacanth to 7 parts of gum acacia, said emulsion having a pH of 5.5 to 6.0.

2. As a composition of matter, an emulsified vitamin D concentrate, containing approximately 32 parts of vitamin concentrate having a strength of approximately 6,000 A. D. M. A. units per gram, 327 parts of aqueous fluid, 7 parts of gum acacia, 1 part of gum tragacanth and hydrogen ion modifying constituent to produce a pH of 5.5 to 6.0.

3. As a composition of matter a smooth stable, high viscosity emulsion of vitamin D concentrate, said emulsion containing 2700 A. D. M. A. units per gram, having a pH of 5.5 to 6.0, and containing as emulsifying agents a minor proportion of gum tragacanth and a major proportion of gum acacia, the minor proportion of gum tragacanth being sufficiently large, when combined with the major proportion of gum acacia, to produce a smooth stable emulsion.

LLOYD A. HALL.

Patented Feb. 11, 1936 **2,030,792**

UNITED STATES PATENT OFFICE

2,030,792

WATER-MISCIBLE VITAMIN PREPARATIONS CONTAINING VITAMIN D

Charles W. Hooper, Sharon, Conn., assignor to Winthrop Chemical Company, Inc., New York, N. Y., a corporation of New York

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10 Claims. (Cl. 167—81)

This invention relates to improvements in water-miscible vitamin preparations containing the lipoid-soluble vitamin D and methods of preparing the same and is a continuation in part of my copending application Serial Number 728,087, filed May 29, 1934. It relates more particularly to water-miscible propanediol and butanediol solutions of vitamin D, which are not only stable but also are more effective than cod liver oil or oil solutions of irradiated or activated ergosterol of similar vitamin D "rat unit" potency for the prevention and cure of rickets in infants.

Vitamin D has usually been administered heretofore in the form of cod liver oil or in the form of solutions of irradiated or activated ergosterol in oils. Concentrates from fish liver or fish liver oils have also been administered in the form of oil solutions of such concentrates. These preparations, however, do not satisfactorily meet the requirements for a marketable product containing vitamin D. It is difficult to administer cod liver oil or oil solutions of irradiated or activated ergosterol to an infant not educated to the use of a spoon and such preparations are often poured or dropped into the infant's mouth with the attendant inaccuracy of dosage due to spilling or drooling. It is also very difficult to administer either cod liver oil or oil solutions of irradiated or activated ergosterol admixed with water, fruit juice, milk, etc., for the reason that neither the oil base nor the vitamin concentrate per se is miscible with water.

My investigations of water-miscible vitamin preparations containing vitamin D have shown that the vehicle employed for the production of such preparations should (1) be non-toxic, (2) be capable of holding a sufficient amount of the vitamin in solution to give the required therapeutic concentration, (3) have a sufficiently high boiling point to prevent vaporization of the solvent and consequent change in the concentration of the preparation, (4) not be too viscous, (5) not be too hygroscopic, (6) be very miscible with water and aqueous solutions, and (7) form stable solutions of vitamin D.

I have now found that the propanediols and certain butanediols satisfy the above requirements and that solutions of vitamin D in propanediols and certain butanediols possess very desirable properties. The vitamin D in such solutions is exceptionally stable and such solutions may be conveniently and accurately fed to infants in water, fruit juice, milk, soups and the like. On dilution with water, aqueous solutions or emulsions, a very finely dispersed suspension or colloidal solution of the vitamins is obtained which persists without flocculation for a considerable period of time. This is very surprising because my researches have shown that other polyhydric alcohols such as ethylene glycol and glycerin cannot be used to produce vitamin D preparations which are satisfactory. My investigations have shown that not all of the butanediols give satisfactory solutions of vitamin D. I have found that solutions of crystalline vitamin D in 2-methyl-1,2-propanediol are completely decomposed after 3 weeks' incubation at 37° C. Such solutions, after being subjected to the indicated conditions, contained little or no vitamin D. For purposes of convenience, the word "butanediol", therefore, is generically employed in this specification to mean the group consisting of 1,2-butanediol, 1,3-butanediol, 2,3-butanediol, 1,4-butanediol and 2-methyl-1,3-propanediol. It is furthermore most surprising to find that even the two propanediols themselves differ, the 1,2-propanediol giving preparations which are considerably more stable than the preparations obtained by using 1,3-propanediol as a solvent.

The preparation of the water-miscible vitamin preparations containing vitamin D is illustrated by the following examples in connection with which, however, it should be noted that the invention is not limited to the specific products the preparation of which is illustrated or to the specific procedures and proportions described, excepting as may be indicated in the appended claims. In this connection it is noted particularly that the invention is not limited to the use of the particular sources named for the vitamin D.

Example 1

Suspend 100 grams of a vitamin A and D preparation (obtainable from cod liver oil, other fish liver oils or fish livers, for example by saponifying with alkalies and extracting the unsaponifiable matter by means of an organic solvent) in 1000 grams of 1,2-propanediol and gently heat the mixture to approximately 40° C. with the exclusion of air by means of an inert gas such as carbon dioxide, for 2 hours. The mixture is then cooled and centrifuged. The resulting clear solution containing the lipoid-soluble vitamins is separated from the insoluble matter and assayed for its vitamin A and D potency. The solution is clear and when mixed with an excess of water or milk yields a very finely dispersed suspension or colloidal solution.

Example 2

Suspend 10 grams of irradiated ergosterol in 1000 grams of 1,2-propanediol. Heat the mixture to approximately 40° C., with the exclusion of air, by means of an inert gas such as carbon dioxide, for two hours. The mixture is then cooled and centrifuged. The resulting clear solution containing the vitamin D is separated from the insoluble matter and assayed for its vitamin D potency. It is then diluted to the desired vitamin D potency with 1,2-propanediol. The solution is clear and when mixed with water or milk yields a very finely dispersed suspension or colloidal solution which persists without flocculation for a prolonged period.

Example 3

300 milligrams of a crystalline antirachitically highly active transformation product of ergosterol such as that described in U. S. Patent 1,902,785 at page 2, lines 44–70, which melts at 116° to 117° C. and has a specific rotation of

$$\left[\alpha\right]_D^{20}=+81.5^\circ$$

in acetone, are dissolved in 1000 grams of 1,2-propanediol at room temperature, with the exclusion of air, by means of an inert gas such as carbon dioxide. The resulting solution is clear and colorless. It has been shown by assay that the solution contains in each gram approximately 12,000 U. S. P. units of vitamin D. The solution shows excellent dispersion qualities in water, milk, etc. One drop containing approximately 300 U. S. P. units of vitamin D forms a water-clear colloidal solution in 30 cc. of distilled water.

In Examples 1, 2 and 3, 1,3-propane-diol may be substituted for 1,2-propane-diol or mixtures of both may be employed to produce solutions which are similar to those described above.

Example 4

Suspend 75 grams of a vitamin A and D preparation (obtained from tuna liver oil by saponifying with alkalies and extracting the unsaponifiable matter by means of an organic solvent) in 1000 grams of 1,2-butanediol, with the exclusion of air by means of an inert gas such as nitrogen, and allow to stand at room temperature in the dark for 48 hours. The mixture is then centrifugalized. The resulting clear solution containing the lipoid-soluble vitamins is separated from the insoluble matter and assayed for its vitamin A and D potency. This solution is clear and when mixed with an excess of water or milk, yields a finely dispersed suspension or colloidal solution.

Example 5

Suspend 10 grams of irradiated or activated ergosterol in 1000 grams of 1,2-butanediol. Allow to stand at room temperature in a tightly stoppered glass container for one week. The mixture is then filtered through cotton until clear. The resulting clear solution containing the lipoid-soluble vitamin D is assayed for its vitamin D potency and adjusted to contain 20,000 U. S. P. vitamin D units per gram by adding a sufficient quantity of 1,2-butanediol. This solution is clear and shows excellent dispersion qualities in water, milk, etc. One gram forms a water-clear solution in 50 cc. of distilled water.

Example 6

250 milligrams of a crystalline antirachitically highly active transformation product of ergosterol such as that described in U. S. Patent 1,902,785 at page 2, lines 44–70, which melts at 116° to 117° C. and has a specific rotation of

$$\left[\alpha\right]_D^{20}=+81.5^\circ$$

in acetone, are dissolved in 1000 grams of 1,2-butanediol at approximately 40° C., with the exclusion of air by means of an inert gas such as carbon dioxide. The resulting clear solution has been shown by assay to contain in each gram approximately 10,000 U. S. P. units of vitamin D. One gram dispersed in 25 liters of milk by stirring prepares a milk uniformly containing 400 U. S. P. units of vitamin D per liter.

In Examples 4, 5 and 6, 1,3-butanediol, 2,3-butanediol, 1,4-butanediol or 2-methyl-1,3-propanediol or mixtures containing more than one of these butanediols may be substituted for the specifically described 1,2-butanediol. As will be evident from Examples 1 and 4, the propane- and butane-diol solutions of vitamin D may also contain vitamin A.

A portion of the propanediols and butanediols in the above described solutions can be replaced by other liquids, such as, for example, water, alcohol, ethylene glycol and glycerine. The use of mixed solvents other than the propanediols and butanediols is not recommended, however, since an excess of any of the above mentioned replacement solvents usually results in unsatisfactory products. The addition of large amounts of water, for example, lowers the solubility of vitamin D in the propanediols and butanediols. The addition of large amounts of ethylene glycol or glycerine produces a like result. Furthermore, vitamin solutions containing such admixed solvents are not as stable as vitamin solutions containing only propanediols and/or butanediols as solvents.

It is evident that the exact source of the vitamin D is not material, since I may employ a naturally occurring vitamin D as found in fish liver oil, an irradiated ergosterol, a vitamin D product prepared by cathode ray activation or any other suitable vitamin D product.

I have thoroughly tested out the above water-miscible propanediol and butanediol vitamin preparations for stability. Relatively old solutions thereof stored in well filled, tightly stoppered amber bottles have retained their full vitamin D potency even at a temperature of 35° C. I have had the solutions tested in the hospital for the prevention and cure of rickets in infants and the results have been most satisfactory. A daily dose of one drop of the preparation, prepared according to Example 3 and containing approximately 300 U. S. P. units of vitamin D, administered in the infant's milk has been found to be just as effective as 750 U. S. P. units of vitamin D administered in the form of cod liver oil when employed clinically as an antiratchitic agent. The preparations are easily administered in the manner outlined above.

I claim:

1. A vitamin D stable water-miscible vitamin preparation containing an antirachitic vitamin D dissolved in a solvent selected from the group consisting of the propanediols, 1,2-butanediol,

1,3-butanediol, 2,3-butanediol, 1,4-butanediol and 2-methyl-1,3-propanediol.

2. A vitamin D stable water-miscible vitamin preparation containing a crystalline antirachitically highly active transformation product of ergosterol which melts at 116° to 117° C. and has a specific rotation of

$$\left[\alpha\right]_D^{20}=+81.5^\circ$$

in acetone, dissolved in a solvent selected from the group consisting of the propanediols, 1,2-butanediol, 1,3-butanediol, 2,3-butanediol, 1,4-butanediol and 2-methyl-1,3-propanediol.

3. A vitamin D stable water-miscible vitamin preparation containing an antirachitic vitamin D dissolved in a propanediol.

4. A vitamin D stable water-miscible vitamin preparation containing a crystalline antirachitically highly active transformation product of ergosterol which melts at 116° to 117° C. and has a specific rotation of

$$\left[\alpha\right]_D^{20}=+81.5^\circ$$

in acetone, dissolved in a propanediol.

5. A vitamin D stable water-miscible vitamin preparation containing an antirachitic vitamin D dissolved in 1,2-propanediol.

6. A vitamin D stable water-miscible vitamin preparation containing a crystalline antirachitically highly active transformation product of ergosterol which melts at 116° to 117° C. and has a specific rotation of

$$\left[\alpha\right]_D^{20}=+81.5^\circ$$

in acetone, dissolved in 1,2-propanediol.

7. A vitamin D stable water-miscible vitamin preparation containing an antirachitic vitamin D dissolved in 1,3-propanediol.

8. A vitamin D stable water-miscible vitamin preparation containing a crystalline antirachitically highly active transformation product of ergosterol which melts at 116° to 117° C. and has a specific rotation of

$$\left[\alpha\right]_D^{20}=+81.5^\circ$$

in acetone dissolved in 1,3-propanediol.

9. A vitamin D stable water-miscible vitamin preparation containing an antirachitic vitamin D dissolved in 1,2-butanediol.

10. A vitamin D stable water-miscible vitamin preparation containing a crystalline antirachitically highly active transformation product of ergosterol which melts at 116° to 117° C. and has a specific rotation of

$$\left[\alpha\right]_D^{20}=+81.5^\circ$$

in acetone dissolved in 1,2-butanediol.

CHARLES W. HOOPER.

UNITED STATES
COURT OF APPEALS FOR THE
DISTRICT OF COLUMBIA

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CLERK

BRIEF FOR THE COMMISSIONER OF PATENTS,
Appellee

In the United States Court of Appeals for the District of Columbia

No. 8267

WALTER F. STRAUB AND W. F. STRAUB & COMPANY, A CORPORATION, APPELLANTS

v.

CONWAY P. COE, COMMISSIONER OF PATENTS, APPELLEE

APPEAL FROM THE JUDGMENT OF THE DISTRICT COURT OF THE UNITED STATES FOR THE DISTRICT OF COLUMBIA

W. W. COCHRAN,
Solicitor, United States Patent Office,
Attorney for Appellee,
United States Patent Office,
Washington, D. C.

CLARENCE W. MOORE,
Of Counsel,
United States Patent Office,
Richmond, Virginia.

INDEX

Page

Introduction 1

Summary of Argument 2

Argument 2

The Claims 2

The Rejections 4

Anticipation and Unpatentability 5

Aggregation 11

Conclusion 15

Authorities cited:

- *Bager et al., In re*, 409 O. G. 295, 18 C. C. P. A. 1094, 47 F. (2d) 951 9
- *Bresnick et al.* v. *U. S. Vitamin Corp.*, 56 U. S. P. Q. 30 5
- *Cox and Clapsadle, In re*, 453 O. G. 3, 22 C. C. P. A. 761, 73 F. (2d) 630 3
- *Didusch, In re*, 494 O. G. 5, 25 C. C. P. A. 902, 94 F. (2d) 812 7
- *Gray et al., In re*, 415 O. G. 220, 19 C. C. P. A. 745, 53 F. (2d) 520 3
- *Kaumagraph Co.* v. *Superior Trade-Mark Mfg. Co., Inc., et al.*, 72 F. (2d) 417 7
- *King et al., In re*, 510 O. G. 961, 27 C. C. P. A. 754, 107 F. (2d) 618 7
- *Lewis, In re*, 543 O. G. 659, 29 C. C. P. A. 1133, 129 F. (2d) 560 11
- *Malmstead* v. *Warner Bros. Co.*, 103 F. (2d) 334 7
- *Mathieson Alkali Works, Inc., The,* v. *Coe*, 497 O. G. 768, 69 App. D. C. 210, 99 F. (2d) 443 8
- *Parker, In re*, 510 O. G. 543, 27 C. C. P. A. 717, 107 F. (2d) 612 7
- *Potts* v. *Creager*, 155 U. S. 597 7
- *Roberts* v. *Ryer*, 91 U. S. 150 7
- *Trattner, In re*, 383 O. G. 4, 58 App. D. C. 355, 30 F. (2d) 879 11
- *Wagner, In re*, 432 O. G. 8, 20 C. C. P. A. 985, 63 F. (2d) 987 9
- *Walker, Ex parte*, 313 O. G. 231, 1923 C. D. 39 11
- *White, In re*, 397 O. G. 5, 17 C. C. P. A. 956, 39 F (2d) 974 11

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- Sec. 4915 R. S. (U. S. C., title 35, sec. 63) 1

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- "*Dennis* v. *Pitner*," 21 J. P. O. S. 963 10
- Rules of Practice in the United States Patent Office (Rule 41) 4
- Shepard and Asp, "Claiming a New Use of an Old Substance," 20 J. P. O. S. 912 10

In the United States Court of Appeals for the District of Columbia

No. 8267

Walter F. Straub and W. F. Straub & Company, a Corporation, appellants

v.

Conway P. Coe, Commissioner of Patents, appellee

APPEAL FROM THE JUDGMENT OF THE DISTRICT COURT OF THE UNITED STATES FOR THE DISTRICT OF COLUMBIA

BRIEF FOR THE COMMISSIONER OF PATENTS

INTRODUCTION

This is an appeal from the judgment (Appellants' App. 40) of the District Court of the United States for the District of Columbia dismissing the complaint (Appellants' App. 2) of appellants, Walter F. Straub and W. F. Straub & Company, which complaint was brought under Section 4915 R. S. (U. S. C., title 35, section 63) and sought to have said court authorize the Commissioner of Patents to issue to appellants, as applicant and assignee, respectively, a patent containing claims 1, 2, 3, 4, 5, 8, and 10 of application, Serial No. 141,439 filed in the United States Patent Office May 8, 1937 (Appellants' App. 6).

SUMMARY OF ARGUMENT

(1) The claims on appeal are very broad, calling for any food product containing honey and vitamin D, as two of many possible ingredients. Claims 1 and 2 are generic claims and unless they are found allowable, claims 4, 5, and 8 need not be considered (Rule 41 of Rules of Practice in the United States Patent Office).

(2) There are two grounds of rejection: unpatentability and aggregation. Bresnick in his patent No. 2,007,108 (Appellants' App. 104) discloses a preparation containing honey and vitamin D. This preparation is a food. The disclosure of this preparation by Bresnick was not "accidental." There is no room in the case on appeal for the rule of "accidental disclosure." The applicable rule of law is that of "double use." That rule precludes the issuance of a patent to appellants, in view of the prior art, including said Bresnick patent.

(3) Parts of a combination must coact or cooperate. The claims on appeal do not express a combination, but merely an aggregation. Appellants have not proved that the effects of honey and vitamin D together are more than additive. Appellants have not established coaction or cooperation between honey and vitamin D.

ARGUMENT

The claims

(1) The appealed claims are copied in the complaint (Appellants' App: 3 and 4). These claims are all very broad. Claim 1, for example, is directed to a food product "comprising" honey and vitamin D.

The quoted term, as used in patent practice, has a nonexclusive meaning; it does not exclude in a claimed product, or composition, other ingredients than those specifically mentioned in the claim (*In re Gray et al.*, 415 O. G. 220, 19 C. C. P. A. 745, 53 F. (2d) 520; *In re Cox and Clapsadle*, 453 O. G. 3, 22 C. C. P. A. 761, 73 F. (2d) 630). Thus, in tests relied upon by appellants in this case to establish the efficacy of the food product expressed by claim 1, and the other claims (*Cf.* Appellants' App. 82 to 91), the food product employed included not only honey and vitamin D but also milk and water.

Appellant Straub's application emphasizes (Appellants' App. 6 and 7) the alleged discovery, to be later discussed herein, that "a food product containing honey and vitamin D has an unusually large and unexpected beneficial effect upon calcium retention and assimilation in the body." Appellants, however, do not seek protection on such an alleged discovery, as such. They claim a food product, of which honey and vitamin D are two parts.

As pointed out in Finding of Fact No. 2 (Appellants' App. 37), the vitamin D may, according to Straub's application (Appellants' App. 8), be added to honey in the form of an alcoholic extract, an oil concentrate emulsified in the honey, and finely divided crystals. These three species are (Finding of Fact No. 3, Appellants' App. 38) claimed in (1) Claims 3 and 10, (2) Claims 4 and 8, and (3) Claim 5. Claims 1 and 2, the remaining claims on appeal, are generic claims, reading on all three species.

Rule 41[1] of the Rules of Practice in the United States Patent Office permits an applicant to claim up to three species in one application, if that application also includes an allowable claim generic to all the claimed species. Since Straub's generic claims 1 and 2 were not allowed, Straub was required to elect one species for prosecution (Finding of Fact No. 4, Appellants' App. 38). He elected species (1) defined by claims 3 and 10. Unless, therefore, this Court finds that claims 1 and 2 on appeal are patentable, claims 4, 5, and 8 need not be considered.

THE REJECTIONS

(2) The District Court found two grounds (Appellants' App. 39 and 40) for rejecting the appealed claims. They were:

> (1) That the claims are either anticipated by or unpatentable over the following patents

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[1] Rule 41 in its entirety reads as follows:

"Two or more independent inventions cannot be claimed in one application; but where several distinct inventions are dependent upon each other and mutually contribute to produce a single result they may be claimed in one application: *Provided*, That more than one species of an invention, not to exceed three, may be claimed in one application if that application also includes an allowable claim generic to all the claimed species. In the first action on an application containing a generic claim or claims and claims to more than one species thereunder the examiner, if he is of the opinion after a complete search that no generic claim presented is allowable, shall require the applicant in his response to that action to elect that species of his invention to which his claims shall be restricted if no generic claim is finally held allowable."

in the prior art, cited in the answer (Appellants' App. 5):

Steenbock	1, 680, 818	(Appellants' App. 95)
Rasky	1, 892, 902	(Appellants' App. 100)
Crane	1, 911, 882	(Appellants' App. 102)
Bresnick	2, 007, 108	(Appellants' App. 104)
Hall	2, 022, 464	(Appellants' App. 107)
Hooper	2, 030, 792	(Appellants' App. 109)

(2) That the claims express a mere aggregation rather than a patentable combination. These grounds will be discussed herein *seriatim.*

ANTICIPATION AND UNPATENTABILITY

The patent to Bresnick, No. 2,007,108[2] (Appellants' App. 104), discloses a medicinal preparation containing fish-liver oils of high vitamin D content, oils which have been treated to concentrate the vitamin D therein (Appellants' App. 104, column 1, lines 25 to 29). He masks the odor and taste of these oils with, in one example (Appellants' App. 105, column 2, lines 9 and 10), grain honey. In common with other specified flavorings, the honey may (Appellants' App. 106, column 1, lines 22 to 26) be 15% of a composition that otherwise includes a vegetable fat, such as cocoa butter, 35–40%, a sweetening, such as sucrose (Appellants' App. 105, column 1, lines 63 to 65), 40%, and fish-liver oils, 5–10%.

Despite its obvious pertinency as an anticipation, at least of claims 1 and 2 on appeal, the patent to Bresnick is subjected to severe attack by appellants.

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[2] This patent has been adjudged invalid by the District Court of the United States for the Southern District of New York. *Bresnick et al.* v. *U. S. Vitamin Corp.*, 56 U. S. P. Q. 30.

Since disposal of appellants' arguments in regard to this patent will serve to show the fallacies in kindred arguments raised against other cited patents, such arguments will now be considered in detail.

In the first place, appellants repeat the argument made before the Board of Appeals (*Cf.* Appellants' App. 36) that Bresnick discloses a medicinal preparation, which is "not suitable as a food." This alleged unsuitability of Bresnick's preparation apparently is ascribed by appellants' witness, Schlutz (Appellants' App. 60), to its oily character. But the claims on appeal, and particularly claims 1 and 2, in no wise exclude oily constituents in a food product "comprising" honey and vitamin D. Moreover, this witness merely asserts that the Bresnick preparation is unsuitable as a food for infants. In accordance with the ruling of the Board, no tenable distinction can be drawn between appellants' claimed product, as a food, and Bresnick's preparation, as a medicine; appellants' product plainly partakes of the nature of a medicine and Bresnick's preparation is recited (Appellants' App. 104, column 2, lines 54 and 55) as being "a solid in the nature of a confection."

Further, appellants contend that Bresnick "never contemplated the combination of honey and vitamin D in substantial proportions or * * * knew such combination would produce any unusual result." As to the question of proportions, this is immaterial, for the claims on appeal recite no proportions; only in the application (Appellants' App. 8, fourth paragraph) are they recited, and even then, no critical proportions are given. As to the other matter, it is not requisite that Bresnick have had such knowledge in order for his patent to be anticipatory of a claim to a food product comprising honey and vitamin D.

In effect, appellants contend that they are entitled to a patent because of an alleged discovery of a new use for a product or composition containing honey and vitamin D: to stimulate and normalize calcium metabolism in the human body. It is not invention to use an old machine for a new purpose (*Roberts* v. *Ryer,* 91 U. S. 150; *Potts* v. *Creager,* 155 U. S. 597, 606); the inventor of a machine is entitled to the benefit of all the uses to which it can be put, no matter whether the uses were known or unknown to him. For the same reasons, an old product, or composition of matter, put to a new use is not patentable *(Kaumagraph Co.* v. *Superior Trade-Mark Mfg. Co., Inc., et al.,* 72 F. (2d) 417; *In re Didusch,* 494 O. G. 5, 25 C. C. P. A. 902, 94 F. (2d) 812; *In re Parker,* 510 O. G. 543, 27 C. C. P. A. 717, 107 F. (2d) 612; *In re King et al.,* 510 O. G. 961, 27 C. C. P. A. 754, 107 F. (2d) 618). The applicability of the same general rule—the doctrine of "double use"—to both mechanical and chemical cases is recognized by the Circuit Court of Appeals for the Second Circuit in its *per curiam* decision in *Malmstead* v. *Warner Bros. Co.* (103 F. (2d) 334). With reference to a prior art patent to one Duff disclosing an elastic insertion in a combined girdle and brassière, the Court said:

> The plaintiff's second answer is that Duff did not understand the function of his elastic insertion, as the plaintiff later disclosed it: it is to promote ease in breathing by freeing the

> movement of the ribs. Though true, that is irrelevant, for—at least in the case of mechanical and chemical inventions—a new use for an old thing can never be patentable. Courts have not, indeed, always observed this limitation, but it is none the less true without exception, for, as we have many times said, the statute itself provides that only an "art, machine, manufacture, or composition" shall be patentable. § 31, Title 35 U. S. Code, 35 U. S. C. A. § 31. *Dwight & Lloyd Sintering Co.* v. *Greenawalt,* 2 Cir., 27 F. 2d 823, 828; *Deitel* v. *La Minuette Trading Co.,* 2 Cir., 37 F. 2d 41; *Hookless Fastener Co.* v. *G. E. Prentice Mfg. Co.,* 2 Cir., 68 F. 2d 940; *Ingersoll-Rand Co.* v. *Worthington Pump & Machinery Corp.,* 2 Cir., 87 F. 2d 320. How far a patent for an "art"—a process or a method—is an exception to the absoluteness of this, we need not consider; we are dealing with a "manufacture."

When the Court below found (Finding of Fact No. 13, Appellants' App. 39) that it would not be an invention to discover that the mixture of honey and vitamin D disclosed by the Bresnick patent when used as food might have an effect upon calcium retention in the human body, the Court was properly applying the foregoing law.

Also, appellants contend that Bresnick's disclosure of mixing honey and vitamin D is a mere "chance" or "accidential" disclosure. "The accidental stumbling onto a fact, or the unintentional statement of a fact, might be considered sufficiently a part of the prior art to require its investigation" (*The Mathieson Alkali Works, Inc.* v. *Coe,* 497 O. G. 768, 69 App. D. C.

210, 99 F. (2d) 443). In regard to the disclosure of the Bresnick patent, which is pertinent to the claims on appeal, there are, however, no circumstances of "accident" or "chance"; Bresnick specifically says (Appellants' App. 105, column 2, lines 9 and 10): "I have found grain honey a satisfactory flavoring." The doctrine of "accidental disclosure" is narrow and is infrequently applied. Two cases in which the Court of Customs and Patent Appeals has considered this doctrine are *In re Bager et al.* (409 O. G. 295, 18 C. C. P. A. 1094, 47 F. (2d) 951) and *In re Wagner* (432 O. G. 8, 20 C. C. P. A. 985, 63 F. (2d) 987). In its opinion in the former case, that Court said:

> As to whether an accidental showing in a drawing is or is not an anticipation of a later invention depends generally upon the facts in each particular case. Without reviewing the authorities cited by the respective parties hereto, it is sufficient to say that they appear to establish the rule that an accidental showing in a prior patent does not anticipate a later invention where the thing so shown is not essential to the first invention, and was not designed, adapted, or used to perform the function which it performs in the second invention, and was neither intended nor appreciated by the patentee, and when the first patent contains no suggestion of the way in which the result sought is accomplished by the second inventor. *Brill* v. *Third Ave. R. Co.,* 103 F. 289; *Edison Electric Light Co.* v. *Novelty Incandescent Lamp Co.,* 167 F. 977; *A. R. Mosler & Co.* v. *Lurie,* 209 F. 364; *Munising Paper Co., Limited* v. *American Sulphite Pulp Co.,* 228 F. 700.

In deciding the latter case, the same Court stated:

> While it is true that drawings may not always be relied upon for anticipation of a later application, *In re Daniel,* 17 C. C. P. A. (Patents) 605, 34 F. (2d) 994, it is also true that if a drawing clearly suggests to one skilled in the art the way in which the result sought is accomplished by a later applicant, it is immaterial whether the prior patentee's showing was accidental or intentional. *In re Bager,* 18 C. C. P. A. (Patents) 1094, 47 F. (2d) 951.

The doctrine of "accidental disclosure" does not apply to the facts of the case at bar. That doctrine here must yield to the doctrine of "double use."[3]

To discuss briefly the other cited patents, the patent to Rasky, No. 1,892,902 (Appellants' App. 100), anticipates claim 1 because it discloses a food product comprising honey and butter; butter contains a small quantity of vitamin D (Appellants' App. 60 and Appellants' App. 96, column 1, lines 7 to 10). Steenbock (Appellants' App. 95) teaches that foods generally may have the antirachitic factor imparted to them by treating them with ultraviolet rays. This teaching would sufficiently suggest the addition of vitamin D to such a food as honey, and to such food products containing honey as those disclosed in the aforesaid Rasky patent and the patent to Crane, No. 1,911,882 (Appellants' App. 102). Crane mixes apricots and honey. These several patents, when combined, render claims 1, 2, and 5 on appeal unpatentable. In conjunction with the Hall patent, No. 2,022,464 (Appellants' App. 107), and the Hooper patent, No. 2,030,792 (Appellants' App. 109), they render claims 3, 4, 8, and 10 unpatentable. The said Hall patent plainty suggests the emulsification of an oil concentrate of vitamin D, as required by claims 4 and 8; while the Hooper patent equally as plainly suggests the preparation of a vitamin D concentrate in the form of an alcoholic extract, as required by claims 3 and 10.

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[3] For further discussion of the doctrine of double use as applied in chemical cases, see "Claiming a New Use of an Old Substance," by P. W. Shepard and N. A. Asp, 20 J. P. O. S. 912, and "*Dennis* v. *Pitner,*" 21 J. P. O. S. 963.

It is respectfully submitted that the claims on appeal are fully met by the prior art, as the trial court found. (Conclusions of Law Nos. 1 and 2, Appellants' App. 39 and 40.)

AGGREGATION

(3) The claims on appeal purport to be drawn to the combination of honey and vitamin D. To render claims for a combination patentable, the parts of the alleged combination must coact or cooperate. Unless there is such coaction or cooperation, the alleged combination is really only an aggregation and, as such, unpatentable. (*In re Lewis*, 543 O. G. 659, 29 C. C. P. A. 1133, 129 F. (2d) 560.) In compositions of matter, such as food products, there must be coaction or cooperation of ingredients, as there must be coaction or cooperation of elements of a machine or device. (*Ex parte Walker,* 313 O. G. 231, 1923 C. D. 39; *In re Trattner,* 383 O. G. 4, 58 App. D. C. 355, 30 F. (2d) 879; *In re White,* 397 O. G. 5, 17 C. C. P. A. 956, 39 F. (2d) 974.)

Appellants' expert witness, Dr. Schlutz, expressed the mere opinion (Appellants' App. 64 and 68), RDQ's 66 and 103) that the association of honey and vitamin D "together produces a physiological response in the intestinal tract that is different from that which is obtained when the person eats honey and takes a vitamin D preparation." No tests were referred to in proof of such opinion. Tests were in order, in view of the clear invitation therefor by the examiner (Appellants' App. 22, last paragraph, 24, first paragraph, and 34, fourth paragraph). Because of the absence of tests, the trial court properly found (Finding of Fact No. 11, Appellants' App. 39) that appellants have not proved that the result obtained from feeding a mixture of vitamin D and honey is more than comes from feeding the two separately, and properly concluded (Conclusion of Law No. 3, Appellants' App. 40) that the claims on appeal express a mere aggregation.

Before the examiner, appellants attempted by affidavits (Appellants' App. 9, 11, 17, and 25) to show coaction of the honey and vitamin D. The animadversions of the examiner upon these affidavits (Appellants' App. 22, 23, 24, 33 and 34), which were accepted by the Board of Appeals (Appellants' App. 36), are likewise applicable to the evidence presented in the trial court for the same purpose.

An analysis of the report (Appellants' Exhibit No. 2, Appellants' App. 81 to 91), which is asserted by appellants' witness, Knott (Appellants' App. 73), to be a summary of all the work on calcium retention done during a five-year period, is revealing. In that report it is admitted (Appellants' App. 91, first paragraph) that a "few individual infants had higher results on corn syrup" than honey "when paired periods were compared," and also admitted (Appellants' App. 89, first paragraph) that "discrepancies in results may partially have been due to inherent differences in individual infant types." Most significant is the conclusion of the report (Appellants' App. 91, last paragraph). The authors merely conclude that "honey is * * * a type of carbohydrate which is well suited to the infant's needs." But honey has long been so recognized (Appellants' App. 77, Q. 19, and Appellants' App. 67, RDQ's 96 and 97), and the conclusion thus is hardly more than a truism.

In the body of the report, rather than as a conclusion, the authors assert (Appellants' App. 91 first paragraph) that "honey would seem * * * to have a definite beneficial influence upon the retention of calcium by young infants." It is submitted that the conditions under which the experiments were conducted would support only such a hesitant statement. The authors did not, as would have been proper, test equal numbers of infants with honey and vitamin D, on the one hand, and corn syrup and vitamin D, on the other; as appears from Chart 3 (Appellants' App. 90), there were 74 cases where the former mixture was used as against 37 where the latter was employed. Moreover, there were no experiments using vitamin D alone, and honey alone, as checks. The contention by appellants in their brief (Page 6, second paragraph) that the mixture of honey and vitamin D has a calcium retaining value not attributable to vitamin D alone, or honey alone, hence derives no support from experimental data. From the patent standpoint, if corn syrup and vitamin D were superior to vitamin D alone, then there would seem to be no invention in substituting honey, another sugar (Appellants' App. 77, Q. 19, Appellants' App. 67, RDQ 96), for the corn syrup, to obtain a result only different in degree.

A five-day metabolism period would appear to be too short to give reliable results, in view of the admitted "idiosyncrasies" which affect calcium retention (Appellants' App. 19, second, third, and fourth paragraphs) and of the possibility of error which might arise from such a simple thing as irregular excretion of urine and feces. Other errors may have been introduced and, indeed, seem to have been introduced by the variations in potency of the vitamin D employed (Appellants' App. 88, first paragraph, 89, first paragraph). In the tests, another uncontrolled variable was the milk employed (Appellants' App. 89, last sentence, and Appellants' App. 90, first paragraph). To support valid conclusions, any series of comparative scientific tests must be carried out under fixed standards and conditions.

Under all the circumstances, it is submitted that the trial court properly found (Finding of Fact No. 11, Appellants' App. 39) that appellants have not established that honey and vitamin D coact or cooperate in any unusual or unexpected manner, and properly concluded that the claims on appeal express a mere aggregation (Conclusion of Law No. 3, Appellants' App. 40).

CONCLUSION

The claims on appeal are flatly met by the prior art, and on this ground alone were properly denied to appellants. However, the claims also express a mere aggregation, and were on this further ground properly so denied. On either or both grounds, the judgment of the trial court should be affirmed.

W. W. Cochran,
Solicitor, United States Patent Office,
Attorney for Appellee.

Clarence W. Moore,
Of Counsel

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